

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON**

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION THIS DOCUMENT RELATES TO WAVE 1	Master File No. 2:12-MD-02327 JOSEPH R. GOODWIN U.S. DISTRICT JUDGE
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EXPERT REPORT OF BRUCE ROSENZWEIG, M.D.

I. BACKGROUND AND QUALIFICATIONS

I am currently an Assistant Professor of Obstetrics and Gynecology at Rush University Medical Center in Chicago, Illinois. My Curriculum Vitae more fully reflects my training, background, and publications. I received my MD degree in 1984 from the University of Michigan in Ann Arbor, Michigan. Following graduation from medical school, I completed an Obstetrics and Gynecology Residency at Michael Reese Hospital in Chicago. In 1988, I attended a one year pelvic surgery fellowship at State University of New York in Syracuse, New York. Following that fellowship, I attended a two year Urogynecology and Urodynamics fellowship at UCLA Harbor General Hospital in Torrance, California. After graduating from the Urogynecology fellowship, I became a faculty member at the University of Illinois in Chicago. I started a Urogynecology program at the University of Illinois and also was the residency program director. In 1998, I went into private practice, and subsequently established a private practice at Rush University Medical Center. I have also worked at John H. Stroger Hospital here in Chicago from May 2003 until November 2010 and Weiss Memorial Hospital as Associate Chair of Gynecology from February 2011 until July 2012. I have published numerous articles

and given numerous lectures on the topics of pelvic organ prolapse, urinary incontinence and repair of pelvic organ prolapse.

Throughout my career, I have performed over a thousand pelvic floor surgical procedures, including abdominal sacrocolpopexy, uterosacral suspensions, sacrospinous ligament fixations, native tissue repairs, biological graft repairs and synthetic mesh repairs. I have also used numerous synthetic pelvic mesh products, including Ethicon's TVT, TVT Obturator, and Prolift. In addition, I have performed over 200 surgeries dealing with complications related to synthetic mesh, including the removal of numerous TVT devices. I was also invited by Ethicon and attended both its Gynecare Prolift Training Seminar and TVT Obturator Seminar in Belgium. In addition, I was also invited and attended a Bard Avaulta training seminar.

A true and correct copy of my CV and Fee Schedule is attached as Exhibit "A." A list of my recent trial testimony is attached as Exhibit "B." A list of the materials I reviewed for this report is attached as Exhibit "C," in addition to any documents identified throughout this report.

II. SUMMARY OF OPINIONS.

In formulating my opinions and preparing this report, I reviewed scientific literature, corporate documents from Ethicon, sample products and depositions of Ethicon employees. The corporate documents, sample products and depositions were supplied to me by counsel. All opinions I have are to a reasonable degree of medical and scientific certainty. I understand discovery is still ongoing in this case, and I reserve my right to amend my opinions if further information is provided in any form including, but not limited to corporate documents, depositions and the expert reports of both Plaintiff and Defense experts.

My expert opinions can be summarized as follows:¹

¹ This is not intended to be an exhaustive recitation of my opinions in this case. The full scope of my opinions are described in further detail in this report, previous deposition testimony, and previous reports on this device.

- A. Ethicon's old construction mesh (Prolene), used in the TVT-Secur, is not suitable for its intended application and not reasonably safe as a permanent prosthetic implant for stress urinary incontinence because it is too rigid or stiff, the pores are too small, it is heavyweight mesh, it degrades over time, and causes chronic foreign body reactions, fibrotic bridging, mesh contracture/shrinkage, biofilm formation and infections.
- B. Laser cutting a mesh as small as the TVT-S increased the rigidity or stiffness of the mesh.
- C. The risks of degradation, chronic foreign body reactions, fibrotic bridging, mesh contracture/shrinkage, biofilm formation and infections were foreseeable risks of harm posed by the mesh, which could have been reduced or avoided by the adoption of the reasonable alternative designs and procedures set forth in my prior report.
- D. Ethicon knew that the old construction (Prolene) was not appropriate for use in its TVT-S device but has failed to modify/change the laser cut mesh to a larger pore, lighter weight, less rigid mesh that would not increase the risk of erosions and sexual dysfunction, degrade, cause excessive foreign body reactions, and cause excessive shrinkage/contraction because of its economic interest in maintaining its competitive advantage in the mid-urethral ("MUS") market and, therefore, Ethicon put profits before patient safety.
- E. Ethicon's warnings and disclosures of adverse events in its TVT-S Instructions for Use ("IFU") have been inadequate based on the adverse reactions and risks associated with the TVT-S that have been known to Ethicon from the time the TVT (the TVT-S' predicate device and foundation for the TVT-S' IFU) was first sold and marketed.
- F. Ethicon did not disclose information to physicians in its IFUs regarding characteristics of the old construction mesh (Prolene) that makes it unsuitable for its intended application as a permanent prosthetic implant for stress urinary incontinence, including that it is too rigid, small pore, heavyweight mesh, it degrades over time, and causes chronic foreign body reactions, fibrotic bridging, and mesh contracture/shrinkage.
- G. The foreseeable risks of harm mentioned above could have been reduced or avoided by providing reasonable instructions or warnings as set forth in my prior report.

- H. Ethicon did not inform physicians and patients that Material Safety Data Sheets (“MSDS”) for polypropylene resin used to manufacture polypropylene meshes warned against use of the mesh in a permanently implanted medical device as it is incompatible with peroxides and that studies showed that it caused sarcomas in laboratory rats.
- I. Ethicon did not properly inform physicians that toxicity testing of the polypropylene mesh revealed that it was cytotoxic.
- J. Ethicon’s promotional materials sent to physicians related to the TVT-S were inaccurate and failed to reveal material information promoted in the materials about complications/risks and conflict of interests regarding data.
- K. Ethicon’s collection and reporting of adverse events and complications to physicians and patients is misleading, inaccurate and incomplete.
- L. The benefits of the TVT-S are outweighed by the severe, debilitating and life changing complications associated with the TVT-S.
- M. For a number of reasons, the TVT-S was poorly designed and was a defective product/medical device. For instance, the TVT-S is more prone to failing and not maintaining the angle of correction at the urethra for control of stress incontinence because the length of the tape and the mechanism of insertion were different from the TVT and TVT-O. The TVT-S also had inadequate fixation and lack of support within the first 12 weeks because of the use of Ethisorb, tape length, and the release mechanism that were all known to affect the anchoring of the TVT-S. Such problems were known to Ethicon and also explained the inferior cure rates Ethicon saw with the TVT-S as compared to its predicate devices. Surgeons, particularly those who had implanted TVTs and TVT-Os, were unaware that additional tension was necessary to implant the TVT-S, resulting in lower cure rates and greater risk of mesh erosion/extrusion. Further, the arrowhead inserter was more likely to cause injury upon insertion and removal.
- N. Ethicon recognized the difficulty of the surgical technique employed to implant the TVT-S and that surgeons with less skill would most likely have greater rates of mesh complications/failures. As such, Ethicon should not have marketed the TVT-S to all doctors. Ethicon failed to properly recruit, train, and monitor surgeons who were convinced by sales representatives that the TVT-S was superior to its predicate devices because it was “less invasive.”

III. BACKGROUND AND TREATMENT OPTIONS FOR SUI

A. STRESS URINARY INCONTINENCE (“SUI”)

Approximately one of three women over 45 years old has some form of urinary incontinence. The majority of those women do not seek medical advice or treatment for a variety of reasons.

In a continent individual, increased abdominal pressure is evenly distributed over the bladder, bladder neck, and urethra. The urethral sphincter is thus able to withstand this pressure and maintain continence. In a person with pure stress urinary incontinence (SUI), either the urethra is hypermobile or the sphincter is intrinsically deficient. In urethral hypermobility, the urethrovesical junction (UVJ) is displaced extra-abdominally, and the increased intra-abdominal pressure is unevenly distributed such that the sphincter can no longer withstand the pressure and urine leaks. With intrinsic sphincter deficiency (ISD), the UVJ is not hypermobile; however, the maximal urethral closing pressure, the Valsalva leak-point pressure, or both are too low to withstand the increase in intra-abdominal pressure and, thus, urine leaks past the sphincter.

SUI is the involuntary leakage of urine during moments of physical activity that increases abdominal pressure, such as coughing, sneezing, laughing, or exercise, in the absence of a bladder contraction. It has been estimated that 14% of women have SUI. SUI is a common type of urinary incontinence in women. Urodynamic proven SUI is found in approximately 50% of women presenting for evaluation of urinary incontinence. Symptomatic women with SUI have social or hygienic consequence from their urine loss. SUI can happen when pelvic tissues and muscles, which support the bladder and urethra, become weak and allow the bladder “neck” (where the bladder and urethra intersect) to descend during bursts of physical activity (urethral hypermobility). This descent can prevent the urethra from working properly to control the flow

of urine. SUI can also occur when the sphincter muscle that controls the urethra weakens (intrinsic sphincter deficiency). The weakened sphincter muscle is not able to stop the flow of urine under normal circumstances, and when there is an increase in abdominal pressure. Weakness may occur from pregnancy, childbirth, aging, or prior pelvic surgery. It has been estimated that a majority of incontinent women have a combination of urethral hypermobility and ISD. Other risk factors for SUI include chronic coughing or straining, constipation, obesity and smoking. Finally occult or latent SUI is defined as a positive stress test, loss of urine with increased intra-abdominal pressure and between 350-450cc volume in the bladder, after the repositioning of pelvic organ prolapse (usually accomplished with a ring pessary carefully positioned as to avoid compression of the urethra) in an otherwise clinically continent patient.

B. NONSURGICAL TREATMENT OF SUI

There are numerous non-surgical treatments available to women with SUI. First, Pelvic Floor Exercises which is a type of exercise to strengthen the pelvic floor by contracting and relaxing the levator muscles that surround the opening of the urethra, vagina, and rectum. These exercises, commonly referred to as Kegel exercises, improve the pelvic floor muscles' strength and function. Kegel exercises can improve overactive bladders by increasing urethral resistance with can trigger the bladder to relax.

Second, Pessary: A removable device that is inserted into the vagina against the vaginal wall and urethra to support the bladder neck. This helps reposition the urethra to reduce SUI. These can be made of rubber, latex or silicon. Inserted into the vagina, a pessary rests against the back of the pubic bone and supports the bladder. Pessaries are available in various forms, including donut and cube shapes, and must be fitted by a healthcare provider. Some women who have stress incontinence use a pessary just during activities that are likely to cause urine leakage,

such as jogging. Special incontinence pessaries have a ‘knob,’ which fits under the urethra to elevate the midurethral to prevent urine loss.

Third, Transurethral Bulking Agents: Bulking agent injections are applied around the urethra that make the space around the urethra thicker, thus helping to control urine leakage. The effects are usually not permanent.

Fourth, Behavioral Modification: This includes avoiding activities that trigger episodes of leaking. Lifestyle modification can improve stress incontinence symptoms and include quitting smoking, weight loss, and allergy treatment during seasonal allergies.

Fifth, Urinary seals: These are adhesive foam pads, which women place over the urethral opening. The pad creates a seal and prevents the leakage of urine, providing incontinence treatment. The pad is removed before urination and replaced with a new one afterward. The pad can be worn during exercise or physical activity, but not during sexual intercourse.

Sixth, Urethral insert: A thin, flexible tube that is solid rather than hollow (like a catheter) is placed into the urethra to block the leakage of urine. These small plugs are inserted into the urethra by women to prevent leakage, and are removed prior to urination. These inserts can be uncomfortable and may increase the risk of urinary tract infection.

Seventh, Bladder neck support device: This device is a flexible ring with two ridges. Once inserted into the vagina, the ridges press against the vaginal walls and support the urethra. By lifting the bladder neck, it provides better bladder control in women suffering from stress incontinence. The device needs to be sized to fit, and must be removed and cleaned after urination. Bladder neck support devices can be uncomfortable and may cause urinary tract infections.

C. SURGICAL TREATMENT OF SUI

1. THE BURCH COLPOSUSPENSION

Retropubic approaches for the treatment of stress urinary incontinence include the Burch retropubic urethropexy (both open and laparoscopic) and the Marshall-Marchetti-Krantz (MMK) procedure. The goal of both of these procedures is to suspend and stabilize the urethra so that the urethrovesical junction (UVJ) and proximal urethra are replaced intra-abdominally and to recreate a firm backstop for intra-abdominal pressure. This anatomic placement allows normal pressure transmission during periods of increased intra-abdominal pressure restoring continence in a previously incontinent, hypermobile UVJ.

The Burch procedure was described in 1961. Initially, Burch described attaching the paravaginal fascia to the arcus tendineus. However, this was later changed to Cooper's ligaments because these were felt to provide more secure fixation points, and less chance of infection as seen with the prior MMK procedure.

Patients with type III stress urinary incontinence (a fixed, nonfunctioning proximal urethra) are not ideal candidates for a Burch procedure as no hypermobility exists to correct. For the Burch procedure, a low Pfannestiel incision is made above the pubic bone in order to enter the space of Retzius (the anatomical space between the pubic bone and the bladder above the peritoneum in order to suspend the bladder and/or to perform a paravaginal repair. The procedure involves placing permanent stitches adjacent to the neck of the bladder and either proximal or distal to the bladder neck stitches on each side and suturing them Cooper's ligament which is attached to the pubic bone. The paravaginal repair is very similar except that the stitches are attached to the arcus tendentious linea pelvis. The likelihood of success of the Burch and the paravaginal repair procedures is reported to be 80-90% in most cases. Success means total elimination of the incontinence and patient satisfaction score greater than 90%. Improved means

significant reduction of urine loss and greater than 70% improvement of patient satisfaction scores. Additionally, these retropubic procedures can be accomplished by the laparoscopic route. With respect to the selection of synthetic absorbable suture versus non-absorbable suture, and braided versus monofilament, no prospective randomized blinded data exist to suggest superiority of one suture material over another. However, recognized risks are associated with bone anchors. Modifications in the technique can be used if co-existent central defect cystocele is present and obliteration of the cul-de-sac can be performed to prevent enterocele or posterior vaginal wall prolapse after Burch colposuspension.

2. PUBOVAGINAL SLING PROCEDURES

Pubovaginal slings have excelled overall success and durable cure. The procedure involves placing a band of autologous, allograft, xenograft or synthetic material directly under the bladder neck (ie, proximal urethra) or mid-urethra, which acts as a physical support to prevent bladder neck and urethral descent during physical activity. This is brought up through the rectus fascia. The sling also may augment the resting urethral closure pressure with increases in intra-abdominal pressure.

Historically, surgeons have used the fascia lata sling for recurrent SUI after a failed anti-incontinence operation. Furthermore, this operation is used extensively for the treatment of primary ISD. If the abdominal tissues are weak and attenuated or if the vaginal tissues are atrophied or in short supply, constructing a pubovaginal sling from the leg fascia lata can be performed. This procedure is more involved than the creation of the rectus fascial sling as it requires a second incision to harvest the fascia lata and healing in an area remote for the index procedure.

An alternative to a long rectus sling is construction of a short sling from a much smaller piece of abdominal fascia (rectus fascia suburethral sling). The surgical procedure is similar to that used for the rectus fascia pubovaginal sling, except that the harvested fascial tissue is much smaller and the operation time shorter. The advantage of this procedure is its simplicity. No extensive dissection in the suprapubic area is necessary, and the postoperative result is similar to that of the full-length fascial strip sling.

An alternative to a long fascia lata sling is the use of a postage stamp-sized patch of fascia lata from the outer thigh (fascia lata suburethral sling). The surgical procedure is similar to that for the fascia lata pubovaginal sling, except the harvested fascia is much smaller. This operation does not require extensive dissection in the thigh area, and the postoperative result is similar to that of the full-length fascia lata strip sling. Postoperative convalescence is shorter than that of the fascia lata pubovaginal sling procedure.

The vaginal wall suburethral sling helps restore urethral resistance by increasing urethral compression and improving mucosal coaptation of the bladder neck. This operation is attractive because it is simple and easy to perform. Postoperative complications are minimal, and the recuperative period is short. Vaginal sling surgery is relatively contraindicated in elderly women with atrophic vaginitis. If recognized before surgery, the atrophied vaginal wall may be revitalized with the administration of vaginal estrogen cream or tablets for 3-6 months.

A clear contraindication to pubovaginal sling surgery is pure urge incontinence or mixed urinary incontinence (MUI) in which urge is the predominant component. An inherent risk of any sling procedure is de novo or worsening urge symptoms; thus, surgeons must identify and treat the presence of an urge component before surgery.

Conversely, poor detrusor function is a relative contraindication to pubovaginal sling surgery because the potential for urinary retention is increased. Women with absent or poor detrusor function in the presence of SUI are at a higher risk of experiencing prolonged postoperative urinary retention.

3. MIDURETHRAL SYNTHETIC SLINGS

Based on the “Integral theory of female incontinence,” Prof. Ulmsten developed a midurethral procedure to treat stress urinary incontinence. The first reports of this procedure appeared in 1996 as an intravaginal slingoplasty. The “tape” was placed through a small vaginal incision at the midurethra, brought through the urogenital diaphragm through the retropubic space and exited through small suprapubic incisions. The operation was theorized to correct incontinence by recreating the midurethral support of the pubourethral ligament and also by creating a midurethral hammock for support of the urethra during stress events. The procedure was described to have a success rate of 85-90% with an additional 5-10% significantly improved. The Gynecare TVT system was introduced in the US in November of 1998. Early studies showed that the risk of bladder perforation during the procedure occurred in 5-10% of cases and vascular injury with hematoma formation occurring in 2-5% of patients.

In an attempt to decrease the risk of bladder perforation and vascular injury, a “top-down” approach to trocar placement was promoted as the SPARC procedure, introduced in the US in 2001 by American Medical Systems (AMS). The next modification of the midurethral sling came in 2001 when Delorme described his results for the use of the obturator membrane and inner thigh for passage of the sling material. The proposed advantage was avoidance of the retropubic space, thus avoiding bladder perforation and retropubic vascular injury. The trocars

were passed from the inner thigh through the obturator membrane from an “outside – in direction.”

The next modification came from de Leval in 2003, with the “inside-out” trocar placement for the transobturator sling. This modification came around 2006 with the release of the mini-slings, or single incision slings, which use support devices at the ends of shorter mesh lengths to accomplish fixation without the need for a secondary cutaneous exit point. The mini-slings could be placed in a retropubic or “U” fashion or a hammock or “H” fashion.

IV. EXPERT OPINIONS

A. ETHICON’S PROLENE MESH WAS NOT SUITABLE FOR ITS INTENDED APPLICATION.

Polypropylene mesh (Prolene), the same mesh used in the TVT-S, has many characteristics that make it unsuitable for use as a product intended for permanent implantation in the human vaginal floor. These characteristics include the following: (1) excessive rigidity of laser-cut mesh; (2) degradation of the mesh; (3) chronic foreign body reaction; (4) infections and bio-films; (5) fibrotic bridging leading to scar plate formation and mesh encapsulation; and (6) shrinkage/contraction of the encapsulated mesh.

As a result of these and other inadequacies with the mesh, and for the reasons set forth below, it is my opinion to a reasonable degree of medical certainty that the Prolene polypropylene mesh in the TVT-S causes a multitude of injuries, including the possibility of multiple erosions that can occur throughout one’s lifetime, chronic and debilitating pelvic pain, recurrence, worsening incontinence, chronic dyspareunia, wound infection, rejection of the mesh, sexual dysfunction, urinary and defecatory dysfunction, vaginal scarring, wound healing problems, injury to ureters, pelvic abscess formation, risk of infection, and/or the need for

additional surgeries, among others. As a result, Ethicon's TVT-S (Prolene) is not suitable for its intended application as a permanent prosthetic implant for stress urinary incontinence in women.

1. LASER-CUT MESH

The Prolene mesh in the TVT-S is laser-cut in the manufacturing process, as opposed to being mechanically cut.² This means that the plastic mesh is cut into strips using a laser instead of a cutting blade.³ The result is that the mesh itself is stiffer than mechanically cut mesh.⁴ Internally, Ethicon noted that laser cut mesh "was about three times stiffer than the machine-cut TVT mesh."⁵ However, Ethicon decided against conducting clinical testing to establish the safety and efficacy of the devices affected by using the laser cut mesh.⁶ In fact, the difference in the stretch profile between mechanically cut and laser-cut mesh led Carl G. Nilsson and Christian Falconer, two of the inventors of the original TVT,⁷ and Jean de Leval, the inventor of TVT-O refused to use and questioned the use of laser-cut mesh.⁸ Moreover, according to the J&J Defendants, use of the laser-cut mesh would make them unable to rely on the original studies and data they use to tout the safety and effectiveness of the original TVT.⁹ Even though, laser-cut mesh was never assessed on its own in a clinical trial.¹⁰ Finally, the rigidity of the laser-cut mesh can cause a higher incidence of erosion and sexual dysfunction than mechanically cut mesh.¹¹

2. THE PROLENE MESH IN TVT-S DEGRADES OVER TIME

² ETH.MESH.03941617; Deposition of Dan Smith, May 15, 2014, 48:11-17.

³ Deposition of Dan Lamont, September 11, 2013, 12:13-13:14.

⁴ ETH.MESH.01809080-01809081.

⁵ ETH.MESH.01809080-ETH.MESH.01809081.

⁶ ETH.MESH.01221735-ETH.MESH.01221740.

⁷ Ulmsten U, Falconer C, Johnson P, Jomaa M, Lanner L, Nilsson CG, et al. A multicenter study of tension-free vaginal tape (TVT) for surgical treatment of stress urinary incontinence. *Int J Urogynecol J Pelvic Floor Dysfunct* 1998;9:210-3.

⁸ ETH.MESH.16416002-16416004; ETH.MESH.04048515-0404852; ETH.MESH.03941617.

⁹ ETH.MESH.06040171-06040173.

¹⁰ ETH.MESH.03941617.

¹¹ ETH.MESH.00294195-00294203; ETH.MESH.00271641; ETH.MESH.00328895; ETH.MESH.03916716.

The mesh used in the TVT-S was originally designed in 1974 for use in the abdomen for treatment of hernias, and it has not changed since then.¹² Ethicon describes this mesh as the “old, old” mesh: “The first generation (old, old) mesh is utilized currently in the TVT product....”¹³ The current Material Specifications for TVT-S Mesh list it as: “Old Construction PROLENE* Mesh.”¹⁴ Dan Smith testified that even when the original hernia mesh was updated for use in the abdomen, Ethicon continued to use the “old, old” mesh for TVT-S and does to this day, as follows:

Q: So TVT kept the old when hernia changed to the new.

A: Also known as original, yes.

Q: The mesh that was used in the TVT-R is called sometimes by Ethicon in documents old construction or original mesh; correct?

A: Yes. Yes.¹⁵

In the late 90’s, Ethicon determined that, in the hernia applications, it was safer to move to a lighter weight, larger pore mesh. Ethicon made a similar determination for meshes to be used in the pelvic floor.¹⁶ However, Ethicon never updated the “old, old” hernia mesh used in the TVT-S.¹⁷ Notably, in my opinion this makes science and information regarding hernia meshes and other pelvic meshes of particular relevance when discussing the TVT-S mesh as Ethicon chose to move to large pore, lighter weight meshes in these areas; however, not for the TVT-S.

The placement of permanent polypropylene mesh in the human vagina creates problems because of the chemical composition and structure of the mesh and the physiological conditions

¹² Smith Dep. (2/3/2014) 723:9-724:6.

¹³ Smith Dep. (2/3/2014) 723:9-724:6.

¹⁴ ETH.MESH.10633520 at 3522.

¹⁵ Smith Dep. (2/3/2014) 723:9-724:6.

¹⁶ See, e.g., ETH.MESH.07455220 (discussing mesh shrinkage/contracture and stating: “Since this phenomenon occurs most frequently in small pore, heavy weight mesh, ETHICON has developed large pore, light weight meshes, i.e. GYNECARE GYNEMESH PS Nonabsorbable Prolene Soft Mesh....”).

¹⁷ Smith Dep. (2/3/14) 829:16-829:19.

of the vagina and the surrounding tissues. There have been numerous studies over the last 30 years which have shown polypropylene to be chemically reactive and not inert, with flaking and fissuring demonstrated by scanning electron microscopy, which leads to degradation and release of toxic compounds into pelvic tissues. This process enhances the inflammatory and fibrotic reactions within the tissues in the pelvic floor, causing a multitude of problems.¹⁸ There have been studies suggesting that oxidation of the mesh occurs because of the polypropylene and the conditions in which it is placed.¹⁹ The oxidation causes the mesh to degrade, crack and break apart.²⁰ In a recent study, 100 pelvic mesh implants were compared and over 20% showed degradation to mesh fibers.²¹

Because of the structural complexities of the vagina and the nature of the chemicals ordinarily found in the vagina and its surrounding tissues, there are several reasons why polypropylene presents unique problems when placed in the vagina. An Engineering Bulletin from Propex, entitled “*EB-405, The Durability of Polypropylene Geotextiles for Waste Containment Application*,” from 2011, states that, “[P]olypropylene is vulnerable to the following substances: highly oxidized substances such as (peroxide), certain chlorinated hydrocarbons (halogenated hydrocarbons), and certain aromatic hydrocarbons.”²² It is well known to physicians with expertise in the pelvic floor that vaginal and perivaginal tissues are ready sources for peroxide. The vaginal species lactobacillus produces hydrogen peroxide and lactic

¹⁸ Coda A., *Hernia* 2003;7:29; Jongebloed, WL, “*Degradation of Polypropylene in the Human Eye: A SEM Study*,” *Doc. Ophthalmol.*, 1986 64(1:143-152); Skrypunch, O.W., “*Giant Papillary Conjunctivitis from an Exposed Prolene Suture*,” *Can. J Ophthalmology*, 1986 21(5: 189-192).

¹⁹ Costello C., *et al.*, “*Characterization of Heavyweight and Lightweight Polypropylene Prosthetic Mesh Explants from a Single Patient*,” *Surgical Innovation*, 2007, 143:168- 176).

²⁰ *Id.*

²¹ Clavé A, Yahi H, Hammou JC, Montanari S, Gounon P, Clavé H, “*Polypropylene as a Reinforcement in Pelvic Surgery is Not Inert: Comparative Analysis of 100 Explants*,” *J Biomed Mater Res B Appl Biomater*, 2007, Oct 83(1:44-9).

²² *Citing Schneider H., Long Term Performance of Polypropylene Geosynthetics, "Durability and Aging of Geosynthetics, Koerner, RM, Ed., (Elsevier 1989) 95-109.*

acid from collagen that is produced in the squamous cells of the vagina. Estrogen is the catalyst for the production of collagen from the vaginal cells. It is also well known that hydrogen peroxide produced by the lactobacillus species is important in controlling the vaginal micro-flora.

In fact, the vagina is a ready source of hydrogen peroxide production. In a manuscript from M. Strus, "*The In Vitro Effects of Hydrogen Peroxide on Vaginal Microbial Communities*," the authors show the amount of hydrogen peroxide produced by the lactobacillus species.²³ "Hydrogen Peroxide reached concentrations of from 0.05 to 1.0 mm, which under intensive aeration increases even up to 1.8 mm."²⁴ These results confirmed the previous results of M. Strus in the publication, "*Hydrogen Peroxide Produced by Lactobacillus Species as a Regulatory Molecule for Vaginal Micro-flora*," Med Dosw Mikrobiol, 2004: 56 (1:67-77).

It is also known that aromatic hydrocarbons can be found in the human body. In a paper from HB Moon entitled, "*Occurrence and Accumulation Patterns of Polycyclic Aromatic Hydrocarbons and Synthetic Musk Compounds in Adipose Tissues of Korean Females*," *Chemosphere* 2012 (86:485-490), these aromatic hydrocarbons were noted to be present in, "[t]otal concentrations of PAHs and SMCs in adipose tissues rang[ing] from 15 to 361 (mean:119) ngg(-1) lipid weight and from 38 to 253 (mean:106) nng(-1) lipid weight respectively.... The results of this study provide baseline information on exposure of PAHs and SMCs to the general population in Koreans."

It has also been determined that halogenated hydrocarbons can be found not only in adipose tissue but also the blood stream. A paper entitled, "*Determination of Volatile Purgeable Halogenated Hydrocarbon in Human Adipose Tissue and Blood Stream*," from the *Bulletin of*

²³ Strus, M., et al., *The In Vitro Effect of Hydrgen Peroxide in Vaginal Microbial Communities*, FEMS Immunol Med Microbiol, 2006 Oct; 48(1:56-63).

²⁴ *Id.*

Environmental Contamination and Toxicology, Volume 23, Issue 1, pp 244 – 249 published in 1979, found halogenated hydrocarbons, pesticide by-products, both in human adipose tissues and the blood stream. In a subsequent paper from 1985 in *Environmental Health Perspectives*, Volume 60, pp. 127-131, Henry Anderson, in his paper entitled, “*Utilization of Adipose Tissue Biopsy and Characterizing Human Halogenated Hydrocarbon Exposure*,” also found these pesticide by-products in human adipose tissue. Accordingly, the body location where the polypropylene mesh is being placed can expose it to known chemical degradation agents.

However, chemical degradation is not the only way that polypropylene degrades *in vivo*. In a paper from N Das in the Journal of Biotechnology Research International, Volume 2011, Article ID 941810, entitled, “*Review Article: Microbial Degradation of Petroleum Hydrocarbons Contaminant: An Overview*,” found that various bacteria such as *Pseudomonas* species, *Bacillus* species, *Mycobacterium* and *Corynebacterium* species, which are present in a woman’s vagina, can degrade petroleum hydrocarbons. Also fungi such as the *Candida* species, also present, can degrade petroleum-based hydrocarbons.²⁵ Microbial agents that can be found inside the normal and abnormal flora of the human vagina such as *Candida* and, with certain pelvic infections such as *Bacillus* and *Pseudomonas*, can be a source of biological degradation of polypropylene products.

A paper entitled, “*Health, Safety and Environment Fact Sheet: Hazardous Substances - Plastics*,” from CAW/TCA (www.caw.ca), August 2011:343, found that polypropylene degradation products and residues can form carbon monoxide, acrolein, aldehydes and acids, qualifying these health hazards as toxic and irritants. In a paper from D Lithner in 2011 at 4, entitled, “*Environmental and Health Hazards of Chemicals in Plastic Polymers and Products*,”

²⁵ Das, N , et al., *Review Article: Microbial Degradation of Petroleum Hydrocarbon Contaminants: an Overview*, J Biotech Res Intl, 2011, Article ID 941810, 1-13.

University of Gothenburg, it is stated that, “[n]on-biodegradable polymers can be degraded by heat, oxidation, light, ionic radiation, hydrolysis and mechanical shear, and by pollutants such as carbon monoxide, sulphur dioxide, nitrogen oxide and ozone. This causes the polymer to get brittle, to fragment into small pieces and to release degradation products.” (Citations omitted.) Lithner continues, “[o]ther substances (besides monomers) are often needed for polymerization to occur, for instance initiators, catalysts, and, depending on manufacturing process, solvents may also be used. The resulting plastic polymer can be blended with different additives, for instance plasticizers, flame retardants, heat stabilizers, antioxidants, light stabilizers, lubricants, acid scavengers, antimicrobial agents, anti-static agents, pigments, blowing agents and fillers, and is finally processed into a plastic product. There are many different plastic polymers and several thousand different additives, which result in an extremely large variation in chemical composition of plastic products.” *Id.* at 6 (citations omitted). “Since plastic products are composed of many different chemicals, and the main part of these [are] broken down into something completely different; this complicates the prediction.” *Id.* at 8. “The type and quantity of degradation products formed may also be influenced by degradation mechanisms, presence of polymerization impurities, and surrounding factors, e.g. temperature and oxygen.” *Id.* at 9. “Few studies combining leaching tests with toxicity tests have been performed on plastic products.” *Id.* at 12. The available peer-reviewed literature regarding degradation/oxidation of polypropylene in the human body dates back to the 1960’s and has been reported in numerous such publications.²⁶

Two of the more important and salient articles regarding reported degradation in explanted surgical meshes (hernia and pelvic floor) are the Costello and Clave articles. In his

²⁶ Liebert, T, et al., *Subcutaneous Implants of Polypropylene Filaments*, J Biomed Mater Res. 1976 (10:939-951); Williams, D., *Review of Biodegradation of Surgical Polymers*, J Materials Sci, 1982 (17:1233-1246); Oswald, H.J., et al., *The Deterioration of Polypropylene By Oxidative Degradation*, Polymer Eng Sci, 1965 (5:152-158).

paper, “*Characterization of Heavyweight and Lightweight Polypropylene Prosthetic Implants from a Single Patient*,” Prof. C Costello reported that hernia mesh made of polypropylene oxidized and degraded as a result of the metabolites produced by phagocytic cells during the body’s inflammatory reaction to the mesh. High-magnification photographs showed cracking and peeling of the polypropylene fibers. Ethicon referenced this article in internal emails.²⁷

Another article by A Clave, “*Polypropylene as a Reinforcement in Pelvic Surgery is Not Inert: Comparative Analysis of 100 Explants*,” also displayed high magnification photos of polypropylene fibers from explanted meshes and, in this case, the meshes were explanted from women’s pelvic floor tissue.²⁸ The heavyweight meshes showed even greater cracking than the lower density meshes, but according to Prof/Dr. Clave, ALL 84 of the polypropylene explants examined showed degradation. Oxidation of the implanted mesh due to free radical attack through the synthesis of peroxides, superoxides and hypochlorous acid during the chronic inflammatory phase was listed as just one potential cause for the oxidative degradation within the “septic environment” in which the pelvic meshes are placed.

Given the information available to Ethicon in the scientific and medical literature concerning the potential for degradation of polypropylene, it is my opinion to a reasonable degree of medical certainty that Ethicon should have conducted clinically relevant testing to determine if naturally occurring conditions in the vagina could cause polypropylene to degrade and if so, what the quantity and quality of the products of degradation would be, whether they would be released into surrounding tissues and/or migrate in the woman’s body, what the clinical

²⁷ ETH.MESH.005588123.

²⁸ Clave, A., *Polypropylene as a Reinforcement in Pelvic Surgery is Not Inert: Comparative Analysis of 100 Explants*, I Urogynecol J 2010 21:261-270.

implications for the woman would be and whether some women's body's would react differently to the mesh and degradative process and its by-products.

Ethicon's Daniel Burkley, a Principal Scientist at Ethicon, testified that the science supported the conclusion that mesh could shrink, contract and degrade. Specifically, Mr. Burkley agreed that the risk of degradation increases when you have a severe inflammatory response with mesh implanted in a contaminated field.²⁹ Mr. Burkley also testified that polypropylene mesh in human beings is subject to some slight degree of surface degradation.³⁰ He agreed that degradation might be better understood if Ethicon studied or tested a product that is permanently implanted in women.³¹ In fact, according to Mr. Burkley, Ethicon only conducted one study related to degradation and Prolene material. This study consisted of a Prolene suture implanted into dogs.³² Mr. Burkley testified that the study and photos from the dog actually showed that the Prolene material used in TVT ABBREVO degraded and was still degrading after 7 years.³³

It is now clear from Ethicon's internal documents that Mr. Burkley was incorrect when he said that Ethicon only performed one study related to degradation of Prolene. Contrary to Mr. Burkley's claim, he and other Ethicon scientists were involved in a Prolene human explant study that was conducted in 1987 which found that Prolene degrades while in the body. According to Ethicon's documents, Ethicon's scientists received 58 Prolene human explants from Professor Robert Guidon³⁴ which were analyzed by Ethicon's scientists using scanning electron microscopy ("SEM"). The SEM study revealed that 34 of the 58 Prolene explants (58%) were

²⁹ Burkley Dep. (5/22/13) 184:17-24.

³⁰ Burkley Dep. (5/22/13) 206:2-11

³¹ Burkley Dep. (5/22/13) 206:12-25.

³² ETH.MESH.05453719 (Seven year data for ten year Prolene study: ERF 85-219).

³³ Burkley Dep. (5/23/13) 315:8-13.

³⁴ DEPO.ETH.MESH.00004755

cracked. Further studies, including FTIR and melt point analysis, were conducted by Ethicon's scientists to determine the cause of the cracking observed in Professor Guidon's explants. In a report authored by Mr. Burkley on September 30, 1987, he concluded that the Prolene explants had insufficient antioxidants to protect them from oxidation which led to *in vivo* degradation of the Prolene devices.³⁵ Importantly, Ethicon has not made any changes to Prolene since it was introduced to the market, except that, in 2011, they reduced the amount of Sanatanox (another antioxidant), which could potentially make Prolene more, not less, susceptible to oxidized degradation.³⁶ Thus, Ethicon's internal studies clearly demonstrate that Ethicon's scientists had concluded that Prolene can degrade while implanted in the human body.

Ethicon subsequently hired an outside consulting firm to resolve the cause of the erosion of its surgical meshes for the pelvic floor. In a June 22, 2011 report, PA Consulting Group informed Ethicon that, "[p]olypropylene can suffer from degradation following implant... a process which initiates after a few days post implantation in animal studies."³⁷ The consulting report discusses numerous images of polypropylene mesh that show "physical degradation" of the mesh.³⁸ In addition, in a 2009 presentation, Ethicon Medical Director Piet Hinoul stated that meshes are not biologically inert.³⁹

I have personally seen mesh that is broken, cracked and looks different from when it was in the package. Interestingly, despite years of scientific literature, its own internal dog study and reports from consultants it hired that concluded that the degradation of mesh occurs, Ethicon's Instructions for Use (IFU) continues to claim to this day that the mesh in the TVT-S,

³⁵ ETH.MESH.12831391 at ETH.MESH.1281392

³⁶ ETH.MESH.02589032 and ETH.MESH.07192929 (May 18, 2011 PA Consulting Report: Investigating Mesh Erosion in Pelvic Floor Repair and PowerPoint presentations)

³⁷ ETH.MESH.02589032 and ETH.MESH.07192929 (May 18, 2011 PA Consulting Report: Investigating Mesh Erosion in Pelvic Floor Repair and PowerPoint presentation).

³⁸ *Id.*

³⁹ ETH.MESH.01264260 (Presentation, "Prolift+M," P Hinoul, MD, Ethicon Pelvic Floor Expert's Meeting – Nederland, Utrecht, May 7, 2009).

“is not absorbed, nor is it subject to degradation or weakening by the action of enzymes.”⁴⁰ This is not simply inaccurate, but is false and misleading for all of the reasons stated above, including, most importantly, that Ethicon’s own internal documents and testimony from its employees confirm that the mesh degrades.

It is my opinion to a reasonable degree of medical certainty that the mesh used in TVT-S degrades. The effect of chemical and biological degradation of the TVT-S Prolene mesh in a woman’s tissues can lead to a greater foreign body reaction, enhanced inflammatory response and excessive scarring, which can lead to severe complications in patients, including the possibility of multiple erosions that can occur throughout one’s lifetime, chronic and debilitating pelvic pain, recurrence, worsening incontinence, chronic dyspareunia, wound infection, rejection of the mesh, sexual dysfunction, urinary and defecatory dysfunction, vaginal scarring, wound healing problems, injury to ureters, pelvic abscess formation, risk of infection, and/or the need for additional surgeries, among others. As a result, the polypropylene in Ethicon’s TVT-S mesh (Prolene) is not suitable for its intended application as a permanent prosthetic implant for stress urinary incontinence in women.

Given the information available in the scientific and medical literature concerning the potential for degradation of polypropylene, it is my opinion to a reasonable degree of medical certainty that Ethicon should have conducted clinically relevant testing to determine if naturally occurring conditions in the vagina could cause polypropylene to degrade and if so, what the quantity and quality of the products of degradation would be, whether they would be released into surrounding tissues and/or migrate in the woman’s body, what the clinical implications for

⁴⁰ ETH.MESH.02340568-ETH.MESH.02340590.

the woman would be and whether some women's body's would react differently to the mesh and the degradative process and its by-products.

Moreover, Ethicon failed to inform physicians or patients about the potential for degradation of the mesh and the complications that could follow. In fact, Ethicon not only failed to disclose these risks to physicians and patients, it did not accurately describe these significant risks by calling them "transitory" and by putting inaccurate statements about degradation in its IFU. This is information physicians need to know in order to have a fair and proper conversation with their patients about the use of a product. Physicians rely on device manufacturers to inform them of the risks and complications associated with its products instead of downplaying them or inaccurately stating them. By not disclosing this safety information to physicians and their patients, it is my opinion to a reasonable degree of medical certainty that Ethicon failed to properly inform physicians and patients about the risks of degradation of Prolene mesh in the TVT-S. In addition, by failing to inform physicians, Ethicon did not provide them with an opportunity to discuss these risks with their patients.

3. CHRONIC FOREIGN BODY REACTION

The human body has a natural and fairly predictable "host defense response" to any foreign object placed inside of it. Whether a splinter or a surgical mesh, the human body will send white blood cells to attack the invader and, if the products of inflammation cannot ward off or destroy the invader, including if the invader is anything from bacteria to prosthetic implants, the initial acute inflammatory phase is followed by a chronic inflammatory phase. Therefore, with the placement of something like a permanent surgical mesh in human tissues, there will be a chronic or permanent foreign body reaction to the implant, as well as a chronic inflammatory

response by the body.⁴¹ In fact, Ethicon Medical Directors, Piet Hinoul and Charlotte Owens, have both testified that the chronic foreign body reaction created by the body's response to mesh can cause a severe inflammatory reaction, which can cause chronic pain, nerve entrapment, erosions, dyspareunia and the need for additional surgeries.⁴²

Other consultants and experts in the field informed Ethicon that there would be chronic tissue reaction to its polypropylene meshes. During a 2006 meeting at one of Ethicon's facilities, Bernd Klosterhalfen, a pathology consultant expert for Ethicon, informed Ethicon that there can be a continuing reaction between tissues in the body and mesh for up to 20 years.⁴³ In addition, during a February 2007 meeting, Ethicon stated that there can be, "[E]xcessive FBR [foreign body reaction]> massive scar plate > more shrinkage."⁴⁴

Internally, Ethicon's scientists agreed. Dr. Holste testified that chronic foreign body reactions occurs in Ethicon's small pore, heavyweight meshes like the Prolene mesh found in TVT-S.⁴⁵ In fact, Dr. Holste testified that Ethicon developed lighter weight, large pore meshes in order to minimize the complications seen with heavyweight meshes like the Prolene used in TVT-S.⁴⁶ Ethicon employee, Christophe Vailhe, testified that there can be an excessive inflammatory reaction or foreign body reaction that would lead to mesh erosion

⁴¹ Klinge, U., et al., *Shrinking of Polypropylene Mesh In Vivo: An Experimental Study in Dogs*, Eur J Surg 1998, 164: 965-969; Klinge, U., *Foreign Body reaction to Meshes Used for the Repair of Abdominal Wall Hernias*, Eur J Surg 1998, 164:951-960; Klosterhalfen, B., *The lightweight and large porous mesh concept for hernia repair*, Expert Rev. Med. Devices 2005, 2(1); Binnebosel M, et al., *Biocompatibility of prosthetic meshes in abdominal surgery*, Semin Immunopathol 2011, 33:235-243; ETH.MESH.03658577 (Biocompatibility of Ultrapro).

⁴² Hinoul Dep. (4/5/12) 99:09-25; (4/6/12) 518:14-520:20; (6/26/13) 175:1-176:17; 184:18-22; 328:10-24; Owens Dep. (9/12/2012) 98:11-99:07.

⁴³ ETH.MESH.00870466 (June 6, 2006 Ethicon Expert Meeting Meshes for Pelvic Floor Repair, Norderstedt).

⁴⁴ ETH.MESH.01218361 (Ethicon Presentation: "State of Knowledge in 'mesh shrinkage'-What do we know").

⁴⁵ Holste Dep. (7/29/13) 52:5-55:21.

⁴⁶ Holste Dep. (7/29/13) 51:3-53:6.

and contraction.⁴⁷ Despite its knowledge about the problems associated with chronic foreign body reaction, Ethicon continues to use a heavyweight, small pore mesh in its TVT-S product.

Contrary to this scientific evidence, Ethicon informed doctors in its IFU that its TVT-S mesh was “non-reactive with a minimal and transient foreign body reaction.”⁴⁸ This was despite all of the internal documents and testimony discussed above from Ethicon’s Medical Affairs and Research and Development employees that chronic foreign body reaction occurs in small pore, heavyweight meshes like the Prolene mesh in TVT-S. Moreover, as one of Ethicon’s lead engineers stated: “the foreign body reaction is not transitory – it doesn’t ever go away, but decreases over time to a minimal level.”⁴⁹ That is, it is chronic. I have reviewed numerous pathology reports from my own patients and other physician’s patients and pathology reports reviewed in litigations describing foreign body reactions. Hence, the mesh potentiates a chronic, long-term inflammation. This is contrary to the express language of the TVT-S IFU and, to this date, has yet to be corrected in that IFU.

For the reasons set forth above, it is my opinion to a reasonable degree of medical certainty that the Prolene polypropylene mesh in the TVT-S creates a chronic foreign body reaction which can lead to severe complications in patients, including the possibility of multiple erosions that can occur throughout one’s lifetime, chronic and debilitating pelvic pain, recurrence, worsening incontinence, chronic dyspareunia, wound infection, rejection of the mesh, sexual dysfunction, urinary and defecatory dysfunction, vaginal scarring, wound healing problems, injury to ureters, pelvic abscess formation, risk of infection, and/or the need for additional surgeries, among others. As a result, the polypropylene in Ethicon’s

⁴⁷ Vailhe Dep. (6/21/13) 383:8-19.

⁴⁸ ETH.MESH.02340829.

⁴⁹ ETH.MESH.00211259.

TVT mesh (Prolene) is not suitable for its intended application as a permanent prosthetic implant for stress urinary incontinence in women.

Moreover, Ethicon failed to inform physicians or patients about the potential for a severe, chronic foreign body response and the complications that could follow. In fact, not only did Ethicon fail to disclose these risks, it mischaracterized the risks by calling them “transitory” and by putting inaccurate statements about foreign body response in its IFU. This is information physicians need to know in order to have a fair and proper conversation with their patients about the use of a product. Physicians rely on device manufacturers to inform them of the risks and complications associated with its products instead of downplaying them or inaccurately stating them. By not disclosing this safety information to physicians and their patients, it is my opinion to a reasonable degree of medical certainty that Ethicon failed to properly inform physicians and patients about the risks of foreign body response of Prolene mesh in the TVT-S. In addition, by failing to inform physicians, Ethicon did not provide them with an opportunity to discuss these risks with their patients.

4. INFECTIONS/BIO-FILMS

The placement of midurethral slings, including TVT-S, violates one of the most basic tenets of surgical teachings in that it is the placement of a permanent implant into the human through a “clean contaminated” surgical field, *i.e.* the vagina, which is not sterile and can never be completely sterilized, therefore, implantation through the vagina is contraindicated for every procedure and implantation.

In the TVT-S, the weave of the mesh produces very small interstices which allow bacteria to enter and to hide from the host defenses designed to eliminate them. The bacteria can secrete an encasing polysaccharide slime (biofilm), which further serves to shield the

bacteria from destruction by white blood cells and macrophages.⁵⁰ The effect and consequences of biofilm is to increase the foreign body reaction, resulting in chronic infections, chronic inflammation, erosions, and mesh and scar contracture, and was well known to Ethicon, as evidenced by the testimony of Ethicon's Head of Pre-Clinical, Dr. Joerg Holste.⁵¹

Importantly, the biofilm actually serves as a protection for the bacteria surrounding the mesh fibers against the body's host defense response (white blood cells), which are intended to destroy foreign invaders like bacteria. Thus, the weave induces the creation of a shield against the body's defenses to the bacteria entrained in the woven mesh, inhibiting the body's ability to fight off the infective agents within the mesh. The large surface area promotes wicking of fluids and bacteria which provides a safe haven for bacteria which attach themselves to the mesh during the insertion process.⁵² Daniel Burkley testified that reducing surface area could reduce the amount of chronic inflammation.⁵³ Additionally, the size of the mesh placed equates to a large surface area with many places for bacteria to hide while being protected from host defenses leading to numerous complications.⁵⁴

There have been numerous peer-reviewed journal articles regarding secondary-mesh related infections as well as the dangers of implanting surgical mesh in a clean/contaminated field. Of note, in May of 2013, at the AUA meeting in San Diego, Dr. Shah and his colleagues reported on the "*Bacteriological Analysis of Explanted Transvaginal Meshes*," which

⁵⁰ Osterberg, B., et al., *Effect of Suture Materials on Bacterial Survival in Infected Wounds: An Experimental Study*, Acta. Chir. Scand 1979, 145:7 431-434; Merritt, K., *Factors Influencing Bacterial Adherence to Biomaterials*, J Biomat Appl 1991, 5:185-203; An, Y., *Concise Review of Mechanisms of Bacterial Adhesion to Biomaterial Surfaces*, J Biomed Mater Res (Appl Biomat) 1998, 43:338-348; The TVM Group: J. Berrocal, et al., *Conceptual advances in the surgical management of genital prolapsed*, J Gynecol Obstet Biol Reprod 2004, 33:577-587.

⁵¹ Holste Dep. (7/30/13) 295:24-298:14, 411:15-414:24.

⁵² Klinge, U., et al., *Do Multifilament Alloplastic Meshes Increase the Infection Rate? Analysis of the Polymeric Surface, the Bacteria Adherence, and the In Vivo Consequences in a Rat Model*, J Biomed Mater Res 2002, 63:765-771; Vollebregt, A, et al., *Bacterial Colonisation of Collagen-Coated Polypropylene Vaginal Mesh: Are Additional Intraoperative Sterility Procedures Useful?*, Int Urogyn J 2009, 20:1345-51.

⁵³ Burkley Dep. (5/22/13) 371.

⁵⁴ Klinge, *supra* n. 26; Vollebregt, *supra* n. 26.

included explanted samples of both SUI slings and prolapse meshes. Of the 50 explants examined, 52% of those explanted due to patient complaints' of painful mesh were infused with pathogenic organisms, 20% of those explanted due to vaginal erosions had pathogenic organism, and 83% of those explanted due to urinary tract erosions were contaminated with pathogenic organisms.⁵⁵

When polypropylene particles separate from the surface of the mesh fiber due to degradation, see *infra*, the surface area of the mesh is greatly increased thus providing even greater areas for bacterial adherence to the mesh, more elution of toxic compounds from the polypropylene, and also more of the free toxic polypropylene itself, all of which increases the inflammatory reaction and intensity of the fibrosis.⁵⁶ This cracking of the mesh surface also provides safe harbors for infectious bacteria to proliferate.

In his periodic histopathological analyses for Ethicon of its pelvic floor explants, Dr. Klosterhalfen reported to Ethicon that, in virtually 100% of those instances in which mesh had been explanted due to erosions, he found a secondary, mesh-related infection at the tissue/mesh interface.⁵⁷ Mesh exposure and erosion cause the fibers to be further exposed to bacteria that will adhere to and colonize on the mesh surface.

Ethicon employees have testified that they were aware of these biofilms forming on the surface of the mesh.⁵⁸ However, Ethicon never performed any long-term, clinical studies to determine whether the warnings given them through the peer-reviewed literature and by their own experts and consultants were accurate, namely that mesh-related infections are real; that they cause patient injury in the form mesh erosions and recurrent, late infections; and that the

⁵⁵ Shah, K., et al., Bacteriological Analysis of Explanted Transvaginal Meshes (Abstract 1144).

⁵⁶ Jongebloed, *supra*, n. 1; Sternschuss, G, et al., *Post-Implantation Alterations of Polypropylene in the Human*, J Urol 2012, 188:27-32; Clave, *supra*, at 6.

⁵⁷ ETH.MESH. 00006636.

⁵⁸ Holste Dep. (7/30/13) 283:19-284:5.

transvaginal implantation through and into the non-sterile, septic vagina is below the standard of care for any surgical technique, especially one used to treat non-life threatening conditions, such as stress urinary incontinence.

Therefore, it is my opinion to a reasonable degree of medical certainty that the TVT-S mesh is susceptible to biofilm formation due to the weave of the mesh allowing the infiltration, harboring, and protection of bacterial contaminants; the degraded mesh surface harboring bacteria; the passage through and into a clean/contaminated field; and after exposure/erosion of the mesh into the vagina or other organs, further contamination of the mesh with a multitude of vaginal flora that further increases the risk of harmful and recurrent infections in women. Accordingly, the TVT-S transvaginal technique, as well as the TVT-S mesh itself, are not safe for their intended purpose of implantation into a woman's pelvic tissues and can lead to severe complications in patients, including the possibility of multiple erosions that can occur throughout one's lifetime, chronic and debilitating pelvic pain, recurrence, worsening incontinence, chronic dyspareunia, wound infection, rejection of the mesh, sexual dysfunction, urinary and defecatory dysfunction, vaginal scarring, wound healing problems, injury to ureters, pelvic abscess formation, risk of infection, and/or the need for additional surgeries, among others. As a result, the polypropylene in Ethicon's TVT-S mesh (Prolene) is not suitable for its intended application as a permanent prosthetic implant for stress urinary incontinence in women.

Finally, Ethicon's claims in its IFU that the TVT-S mesh may "potentiate infection" are misleading, at best. If, by the intentionally ambiguous term, "potentiate," Ethicon means "cause," then this is false for all of the reasons stated above. If by "potentiate," Ethicon means "exacerbate an existing infection," then the statement is misleading at best. Ethicon failed to warn physicians and patients that a slimy, protective biofilm could form on the mesh leading to

painful erosions, recurrent, late infections and the need for mesh removal. The TVT-S IFU contrasts sharply with the PROLENE IFU on this issue. The PROLENE IFU states as follows: PROLENE Mesh in contaminated wounds should be used with the understanding that subsequent infection may require removal of the material.⁵⁹

Ethicon did not to include this risk, despite that unlike hernia mesh, TVT mesh is being implanted through a contaminated environment – the vagina. By failing to include this risk, Ethicon did not adequately warn physicians about these important risks, nor by extension, provide surgeons with an opportunity to discuss these risks with their patients.

5. PORE SIZE AND FIBROTIC BRIDGING

Fibrotic bridging occurs when the fibers surrounding the pores of the mesh are too close together to allow the tissue in the pore enough room to recover from the trauma of tissue damage due to implanting a surgical prosthetic device. Pores that are large enough for good, newly-vascularized tissue tend to be filled with fatty tissue versus small pores that become filled with scarred or fibrotic tissue. In those instances, the scar forms across the pores or “bridges” from one side of the pore to the other. This can occur either due to the granulomas around the mesh fibers joining together or due to densely-formed fibroblasts between these granulomas. Either way, such bridging can lead to the creation of a rigid, scar plate that can encapsulate the mesh with scar tissue. Simply put, small mesh pores that cause fibrotic bridging turn the mesh into a solid sheet of scar tissue and there is no space or room for tissue to grow into the mesh, which is the intended purpose of the mesh. The fibrotic bridging and scar plate prevents tissue in-growth and causes complications, including, among other things, pain with the rigid mesh, shrinkage or contraction of the mesh, erosions due to mechanical irritation in the tissue of a rigid, scar-plated mesh, nerve entrapment, chronic pain and dyspareunia.

⁵⁹ ETH.MESH.05920616 (7/20/07 Email from Chomiak, M. re Defining Light Weight Mesh).

This concept is best illustrated by a DVD produced by Ethicon which features an Ethicon consultant, Dr. Todd Heniford, talking about a heavyweight, small pore mesh called Marlex used for hernia repairs.⁶⁰ The Prolene mesh used in TVT-S is of heavyweight, small pore construction and, in fact, is even heavier than Marlex. Ethicon Scientists have acknowledged that the Marlex mesh in the video is similar to the Prolene in TVT-S in that is heavy weight small pore mesh.⁶¹ In the video, Dr. Heniford talks about the dangers of heavy weight, small pore meshes.⁶² In fact, Dr. Heniford states, “there is no excuse for using heavy weight, small pore meshes in the human body.”⁶³

I have explanted numerous TVT meshes and have witnessed meshes with extensive scar plating and mesh encapsulation similar to the hardened/stiffened mesh viewed in the Heniford video. In numerous emails, Ethicon employees discussed concerns regarding fibrotic bridging.⁶⁴ They have testified that the heavy weight, small pore type of mesh in the TVT-S can lead to an increased risk of foreign body reaction, contraction of the mesh, nerve entrapment, erosions and chronic pelvic pain.⁶⁵ In other emails, when discussing these concepts, Ethicon’s World Wide Marketing Director for General Surgery, Marty Chomiak, states that “... we want to avoid

⁶⁰ Heniford, B.T., 2007, *The benefits of lightweight meshes in Ventral Hernia Repair in Ventral Hernia Repair*, Video produced by Ethicon.

⁶¹ ETH.MESH.05918776 (5/04/04 Email from Schiaparelli, Jill, Strategic Grown Subject: Marlex Experience); Batke Dep. (8/01/13) 87:12 - 88:10, 113:3-114:3, 257:23-259:13; Holste Dep (7/29/13) 51:3-53:6, 55:22-57:4; Vailhe Dep. (6/20/13) 182:2 185:5.

⁶² Heniford Video, supra, n. 46.

⁶³ *Id.*

⁶⁴ ETH.MESH.04037600 (Innovations in mesh development); ETH.MESH.05920616 (7/20/07 ; Emails from Chomiak, M. to Batke, B., et al. re Defining light weight mesh); ETH.MESH.05585033 (Boris Batke Presentation – Project Edelweis – Ultrapro); ETH.MESH.05446127 (3/13/2006 Emails from Holste, J. to Engel, D., et al.re Mesh and Tissue Contraction in Animal – “Shrinking Meshes?”); ETH.MESH.05475773 (2/09/2007 Boris Batke, Ethicon R&D, Presentation: *The (clinical) argument of lightweight mesh in abdominal surgery*); ETH.MESH.04015102 (3/1/12 Email from Batke, Boris to Mayes, C. re AGES Pelvic Floor Conference-Gala Dinner Invitation); ETH.MESH.04037600 (3/15/12 Boris, B. PowerPoint Presentation, *Innovations in Mesh Development*, Melbourne AGES 2012).

⁶⁵ Batke Dep. (8/1/13) 87:12-88:10, 113:3-114:3, 257:23-259:13; Holste Dep. (7/29/13) 51:3-53:6, 55:22-57:4; Vailhe Dep. (6/20/13) 182:2-185:5.

‘bridging’, therefore we think large pores are better than small . . .”⁶⁶ Ethicon also had information and scientific knowledge regarding superior mesh designs to prevent fibrotic bridging and scar plating. Specifically, Ethicon also had scientific knowledge that light weight, large pore mesh could decrease the likelihood of foreign body reaction, fibrotic bridging and scar plating.⁶⁷

Despite having clinical knowledge of the importance of pore size to successful outcomes, and dozens of emails about the importance of pore size, Ethicon’s person most knowledgeable about pore size testified that Ethicon does not manufacture its mesh to a specific pore size. Dan Smith testified as follows:

Q: Does Ethicon have a validated test method to determine the pore size of its TVT mesh?

A: We determine the pore size by courses and wales and that is how it's done. So the courses and wale count is a validated test method.

Q: And I'm talking about pore size. Does Ethicon have a validated test method to determine its pore size for its mesh?

A: The construction of the mesh is -- does not have a pore size requirement.⁶⁸

In fact, Ethicon does not even have a test to measure the pore size of its mesh. Dan Smith testified:

Q. Mr. Smith, does Ethicon have a validated test to describe the pore size of its TVT meshes microns? Yes or no.

A. No....⁶⁹

Despite the information that it did not measure pore size or manufacture its mesh to a specific requirement, Ethicon repeatedly stated in advertising and marketing materials that its mesh was “large pore.” For example, in one brochure, Ethicon promotes the mesh used in the TVT family of products (including TVT-S) as the “Largest pore size” of any of its competitors,

⁶⁶ ETH.MESH.05920616 (7/20/07 Email from Chomiak, M. re Defining Light Weight Mesh).

⁶⁷ Batke Dep. (8/1/13) 87:12-88:10, 113:3-114:3, 257:23-259:13; Holste (7/29/13) 51:3 - 53:6, 55:22 - 57:4; Vailhe Dep. (6/20/13) 182:2-185:5.

⁶⁸ Smith Dep. (2-3-14) 729:1 to 729:12.

⁶⁹ Smith Dep. (2-3-14) 779:5 to 779:8.

listing the size as 1379 μm .⁷⁰ However, given that Ethicon has no verified methodology to measure pore size, Ethicon had no scientific basis upon which to base these statements. In fact, in internal documents, Ethicon scientists described PROLENE mesh as small pore: “Standard Mesh PROLENE small pores area weight 105 g/m².”⁷¹ One Ethicon Engineer measured a mesh and determined that there were two pore sizes in the mesh, a “major” and “minor” pore. “There are two distinct pore sizes in the PROLENE 6 mil mesh (TVT). The major pore is about 1176 μm The minor pore is about 295 μm .”⁷² Certainly, neither of these pores was 1379 μm , and the minor pore was substantially smaller.

In summary, for the reasons set forth above, it is my opinion to a reasonable degree of medical certainty that the Prolene polypropylene mesh in the TVT-S causes fibrotic bridging in the body, resulting in an increased inflammatory response leading to a multitude of injuries, including the possibility of multiple erosions that can occur throughout one’s lifetime, chronic and debilitating pelvic pain, recurrence, worsening incontinence, dyspareunia that can be chronic, nerve injury, wound infection, rejection of the mesh, sexual dysfunction, urinary and defecatory dysfunction, vaginal scarring, wound healing problems, injury to ureters, pelvic abscess formation, risk of infection, and/or the need for additional surgeries, among others. As a result, the polypropylene in Ethicon’s TVT-S mesh (Prolene) is not suitable for its intended application as a permanent prosthetic implant for stress urinary incontinence in women.

Moreover, Ethicon did not inform physicians and patients that its mesh was susceptible to fibrotic bridging. Ethicon failed to warn physicians and patients that fibrotic bridging could occur leading to painful erosions, recurrent, late infections, nerve injury and the need for mesh

⁷⁰ ETH.MESH.00349508 at 9510.

⁷¹ ETH.MESH.04941016.

⁷² ETH.MESH.00584175 (Ex. T-3583); ETH.MESH.00584179 (Ex. T-3581).

removal. By failing to do so, Ethicon did not adequately warn physicians about these important risks, nor by extension, provide surgeons with an opportunity to discuss these risks with their patients.

6. MESH CONTRACTURE/SHRINKAGE

Mesh contracture or shrinkage is an event that takes place after the implantation of mesh and relates to the wound healing process that occurs after the surgical trauma of implanting a foreign body made of polypropylene in the sensitive tissues of the vagina and pelvis. By 1998, polypropylene mesh was known to contract or shrink 30-50%.⁷³ These findings were later confirmed in numerous papers, such as those by W Cobb and his colleagues – one of whom was Dr. Henniford (referenced above).⁷⁴ This also showed that heavier weight meshes like TVT-S led to greater amounts of contraction. The works of Cobb and Klinge/Klosterhalfen have been referenced in numerous Ethicon documents. Contraction or shrinkage has been shown to draw nerves close to the midurethral sling mesh both in the transobturator application⁷⁵ and for retropubic application.⁷⁶ Furthermore, contraction or shrinkage is closely related to the pore size and weight of the mesh. Small pore, heavy weight mesh leads to fibrotic bridging which leads to scar plates, mesh encapsulation and shrinkage or contraction of the mesh, which is compounded by the shrinkage effect associated with the normal wound healing process already occurring in the tissue.

⁷³ Klinge, U, *Shrinking of Polypropelen Mesh in Vivo: An Experimental Study in Dogs*, Eur J Surg 1998, 164:965-969.

⁷⁴ Cobb, W., et al., *The Argument for Lightweight Polypropylene Mesh in Hernia Repair*, Surgical Innovation 2005, 12(1):T1-T7.

⁷⁵ Corona, R., et al., *Tension-free Vaginal Tapes and Pelvic Nerve Neuropathy*, J Min Invas Gynecol 2008, 15:3 262-267; Parnell, B.A., et al., *Genitofemoral and Perineal Neuralgia after Transobturator Midurethral Sling*, Obstet Gynecol 2012, 119:428-431; Jacquetin, B, *Complications of Vaginal Mesh: Our Experience*, Intl Urogyn J, 2009, 20:893-6; Tunn, R, *Sonomorphological Evaluation of Polypropylene Mesh Implants After Vaginal Mesh Repair in Women with Cystocele or Rectocele*, Ultrasound Obstetrics Gynecol 2007, 29:449-452.

⁷⁶ Heise, C.P., et al., *Mesh Inguinodynia: A New Clinical Syndrome After Inguinal Herniorrhaphy?*, J Am Coll Surg

This phenomenon of shrinkage and its relation to the design of the pores as well as the consequences to the patient were illustrated in an email by Ethicon Scientist Joerge Holste in a March 13, 2006 email discussing a paper he authored entitled “Shrinking Meshes?”⁷⁷ In his email, Dr. Holste states “this was our scientific statement on mesh shrinkage: Basically, small pores, heavy weight meshes induce more fibrotic bridging tissue reaction causing more mesh shrinkage during maturation of the collagenous tissue. See my presentation about biocompatibility.”⁷⁸ In addition, in a presentation by Boris Batke, Associate Director R&D, he states heavier-weight polypropylene mesh results in mesh contraction of 33%.⁷⁹ In an email dated November of 2002, related to a discussion of mesh used in a TVT product, Axel Arnaud, one of Ethicon’s medical directors, used 30% shrinkage of the mesh as a “rule of thumb.”⁸⁰ At an Ethicon expert meeting in Norderstedt, Germany in 2007, an Ethicon employee presented a PowerPoint entitled “Factors Related to Mesh Shrinkage” in which all of these issues were clearly laid out.⁸¹

Mesh shrinkage was known by Ethicon as early as 1998 in published work by Ethicon’s then consultants, Uwe Klinge and Bernd Klosterhalfen.⁸² They noted in these early papers that all polypropylene meshes shrink 30-50%. This was restated in later works by W Cobb and his colleagues⁸³--one of which was Dr. Heniford (referenced above). The words of Cobb and Klinge/Klosterhalfen have been referenced in numerous Ethicon documents and thus, Ethicon was

⁷⁷ ETH.MESH 05446127, *supra*, n. 34.

⁷⁸ *Id.*

⁷⁹ ETH.MESH 05479717 (3/1/11 Boris Batke, Ethicon Associate Director R&D, Presentation: Ethicon Polypropylene Mesh Technology).

⁸⁰ ETH.MESH 03917375.

⁸¹ ETH.MESH. 02017152 (Nordestadt Expert’s meeting 2007); ETH.MESH.01782867 (Factors Related to Mesh Shrinking).

⁸² Klinge U, Klosterhalfen B, Muller M, Ottinger A, Schumpelick V. Shrinking of Polypropylene Mesh in vivo: An Experimental Study in Dogs. Eur J Surg. 1998; 164; 965-969

⁸³ ETH.MESH.07455220.

well aware of these findings regarding the shrinkage or contraction of polypropylene meshes in vivo. Ethicon was further aware that heavier weight meshes led to greater amounts of contraction.

It is my opinion to a reasonable degree of medical certainty that as a result of work with internal and external experts and consultants in the late 1990s, multiple internal documents and articles, and the scientific literature as a whole, that Prolene mesh used in TVT-S not only could, but would shrink and contract, and that this shrinkage could lead to painful complications in women implanted with TVT-S, such as multiple erosions that can occur throughout one's lifetime, chronic and debilitating pelvic pain, recurrence, worsening incontinence, chronic dyspareunia, nerve injury, wound infection, rejection of the mesh, sexual dysfunction, urinary and defecatory dysfunction, vaginal scarring, wound healing problems, injury to ureters, pelvic abscess formation, risk of infection, and/or the need for additional surgeries, among others.

As a result, the polypropylene in Ethicon's TVT-S mesh (Prolene) is not suitable for its intended application as a permanent prosthetic implant for stress urinary incontinence in women, and Ethicon failed to warn physicians and patients of the possibility of shrinkage and contraction and the adverse outcomes that could occur as a result.

7. ETHICON HAD LIGHTER WEIGHT, LARGER PORE MESHES AVAILABLE

Ethicon did not change the Prolene mesh in its TVT device despite having better and safer options available for economic reasons. Ethicon believed that continued use of the TVT mesh gave the company an economic and competitive advantage in marketing the product because they could continue to use the existing clinical data on the product to market the device, even though because the mesh was changed, the existing clinical data would be obsolete.⁸⁴ Dr. Brigitte Hellhammer testified that despite having incorporated the use of the lightweight, large

⁸⁴ ETH.MESH.03911107

pore Ultrapro mesh in vaginal tissues for the treatment of pelvic organ prolapse, the Ultrapro was never used by Ethicon in a device used for the treatment of stress urinary incontinence largely because the company wanted to continue to rely on the Ulmsten/Nilsson series of studies on 130 patients performed with the TVT device.⁸⁵ Dr. Arnaud also confirmed that the company did not want to change anything with the mesh because of the existing clinical data on the product.⁸⁶ It is my opinion to a reasonable degree of medical certainty that Ethicon was negligent in failing to correct the defects in the TVT mesh as the company had knowledge of the defects and failed to correct the defects with products and solutions that were already available to the company because it valued its economic interests above patient safety.

B. THE TVT-S' IFU LACKED ALL KNOWN RISKS AND WAS INACCURATE.

The purpose of the IFU is for a medical device manufacturer to provide physicians with the information necessary for them to make decisions regarding the use of a medical device for a particular patient. In addition, the IFU should disclose potential adverse reactions and risks known to the medical device manufacturer to the physician so that the risks can be relayed to the patient and an informed decision regarding the use of the product can be reached. Throughout my education, training, surgical and clinical practice, I have reviewed numerous IFUs for a variety of products, including mesh products in order to understand the proper way to use the device and to gain knowledge about the complications and adverse events associated with a device. I have extensive clinical experience with IFUs and instructing patients about the adverse events/risks contained in the IFU. Similar to Medical Directors, Dr. Martin Weisberg and Dr. David Robinson, I have gained expertise in IFUs through my extensive clinical experience

⁸⁵ Deposition of Brigitte Hellhammer, MD, September 11, 2013

⁸⁶ Deposition of Axel Arnaud, July 19, 2013 36:15-37:3

reviewing IFUs, and obtaining patients' consent regarding surgeries, including Ethicon's own pelvic mesh products including the TVT line and Prolift.

Catherine Beath, Ethicon's former Vice President of Quality Assurance and Regulatory Affairs, testified that "physicians should be made aware of all the significant safety risks associated with the product in the IFU."⁸⁷ And, "a reasonably prudent medical device company would continually update the label consistent with developing data and information that becomes known to the company" when it is appropriate.⁸⁸ Similarly, former Medical Director Dr. David Robinson testified that the warnings and adverse event section of the IFU should include all significant risks and complications related to the procedure and the mesh.⁸⁹ According to Dr. Robinson, a device manufacturer must include this information because you want to make sure the doctors have all the information they need to adequately inform patients who are deciding to use the product.⁹⁰ According to Ethicon Medical Director Dr. Martin Weisberg, the goal of the IFU is to communicate the most important safety risks attributable to the TVT device and that an IFU should never exclude known hazards or complications.⁹¹ Dr. Weisberg also believes that an IFU should not knowingly underestimate the risks of using the product.⁹² And, if an IFU excludes known complications or understates the risks, it "fails in one of its principal purposes."⁹³

1. THE IFU DID NOT INCLUDE ALL KNOWN RISKS

As a surgeon who has relied on dozens of IFUs to understand the risk-profile of devices and medications, it is my opinion that Ethicon did not provide physicians and patients with

⁸⁷ Beath Dep. (7/12/13) 592:7-11.

⁸⁸ Beath Dep. (7/11/13) 198: 8-13.

⁸⁹ Robinson Dep. (9/11/13) 238:12-25.

⁹⁰ Robinson Dep. (9/11/13) 239:1-11.

⁹¹ Weisberg Dep. (8/9/13) 659:19-660:15.

⁹² *Id.* at 960:13-16.

⁹³ *Id.* at 961:10-17.

adequate warnings in the IFU for the TVT-S. Despite the importance of an IFU, Ethicon provided only vague potential adverse reactions. If you compare the adverse reactions/risks in the TVT-S IFUs to the adverse reactions/risks that were available and known to Ethicon at the time of the launch of TVT-S, it is clear that there are numerous adverse events absent from the IFU. For example, in the TVT-S IFU at launch, the Adverse Reactions/Risks section reads as follows:

ADVERSE REACTIONS

- Punctures or lacerations of vessels, nerves, bladder or bowel may occur during instrument passage and may require surgical repair.
- Transitory local irritation at the wound site and a transitory foreign body response may occur. This response could result in extrusion, erosion, fistula formation or inflammation.
- As with all foreign bodies and surgical implants, PROLENE Mesh may potentiate or exacerbate an existing infection.
- Over correction, i.e., too much tension applied to the tape, may cause temporary or permanent lower urinary tract obstruction.
- Under-correction or incorrect placement may result in incomplete or no relief from urinary incontinence.

Despite only listing the above adverse reactions/risks, it is clear from the testimony of Senior Ethicon Employees in both the Medical Affairs and Regulatory Affairs that every adverse reaction/risk that Ethicon has scientific knowledge of today, it had scientific knowledge about at the time the TVT was first sold and certainly in 2006 when the first TVT-S was sold, marketed and launched. Medical Director, Piet Hinoul testified that Ethicon understood the following adverse events occurred from the time the TVT was first sold, years before the first TVT-S was sold:

Erosions through vaginal epithelium infection
 Pain
 Urinary Problems
 Erosions that could decrease patient's quality of life
 Dyspareunia
 Need for additional surgeries

- Need for the removal of device
- Urinary Tract Infections
- Dysuria
- DeNovo Urgency
- Mesh Exposure
- Fistula Formation
- Hematoma
- Abscess Formation
- Narrowing of vaginal wall
- Erosion which can occur any time in future
- Contracture of mesh causing pain
- Complications making it impossible to have sexual relations
- Worsening Incontinence

Yet, none of these were in the TVT-S IFU at launch.⁹⁴

It was unreasonable on Ethicon's part to expect surgeons, even highly skilled ones, to know of all the potential complications of the TVT-S product and procedure simply because of their profession as doctors. In this respect, the IFU failed to warn of a number of risks associated with the use of the TVT-S to treat SUI such as mesh shrinkage/contraction, degradation of the polypropylene mesh over time, chronic pelvic pain, dyspareunia, untreatable and permanent pain, partner penile injury with intercourse, vaginal scarring, narrowing, shortening, fibrosis, scar plate formation, deformation, that the safety and effectiveness of the TVT-S had not been evaluated in either long-term clinical studies or a Randomized Control Trial ("RCT"), chronic foreign body reaction and the potential long-term consequences associated with such a foreign body reaction, the necessity of multiple surgeries to remove mesh and other complications stemming from these surgeries, that some risks were unknown due to the lack of RCTs conducted on this product, the incision size should be at least 1.5 cm, complications could appear at any time into the future and could last for the remainder of the patient's life, and the higher failure rates and reoperation rates associated with the TVT-S as compared to the TVT and TVT-

⁹⁴ETH.MESH.01037447 Page 6; *see also* Deposition of Charlotte Owens 6.19.13 Page 178 Line 10-14.

O. Of course, the IFU failed to warn about the potential permanency of any of the risks in the IFU.

Indeed, Medical Director Dr. Weisberg testified that Ethicon did not include: “permanent, lifelong, worsening and debilitating pain,” lifelong risk of surgical repairs for erosions, “severe or chronic inflammation,” fibrotic bridging, that the product can degrade, or cause severe erosion.⁹⁵ In addition, former Medical Director, Dr. David Robinson, testified that Ethicon never informed physicians that patients may require multiple surgeries to treat erosions, that erosions could be severe and untreatable, and that patients could endure lifelong severe pain or dyspareunia. This is true despite, as discussed above, Ethicon having scientific knowledge of the risks at the time of launch.

2. THE IFU INACCURATELY PORTRAYED RISKS

Internal documents show that Ethicon employees knowingly failed to disclose the TVT-S’ inadequacies. When Dan Smith visited Australia, he discovered that Australian doctors were executing the procedure incorrectly. Ethicon’s documents reveal that in Mr. Smith’s opinion, his visit addressed concerns doctors were experiencing.⁹⁶ Communications between Dan Smith and Mark Yale, Risk Management Director, inquired whether the team is “aligned with what Dan [Smith] is communicating.” Dr. Aran Maree responds that they are not “aligned” and details the differences in his response. Specifically, Dr. Maree referenced that Key Opinion Leader (“KOL”) Professor Frazer reported to Dr. Maree that “the IFU is fundamentally misleading” and that “tension-free, tension-less and placement with no tension are complete misnomers.”⁹⁷ Ethicon found that too much tension applied to the tape may cause temporary or permanent

⁹⁵ Weisberg Dep. (8/9/13) 968:12-972:21.

⁹⁶ ETH.MESH.00311792 Page 3

⁹⁷ *Id.*

lower urinary tract obstruction. To the contrary, not enough tension or incorrect placement would result in incomplete or no relief from urinary incontinence.

This correspondence among other internal documents⁹⁸ outline a wide discrepancy between what Dan Smith reported back to David Robinson and others in the United States and information Dr. Maree (in Australia) was learning from conversations with the same people.⁹⁹ Dr. Maree noted on November 2, 2007, “[i]t is my understanding that some suggestions had come out in the form of (i) increased tension required with this mesh with ‘pillowing of peri-urethral tissues required,’ (which is quite the opposite of TVT-O recommendations), as well as (ii) new tips and tricks to avoid dislodging the device when removing the inserters and (iii) new tips for minimal dissection when introducing the product. We also discussed the fact that at this time some or all of these suggested changes may not be incorporated into the [IFU] or technical training material.”¹⁰⁰ Despite these known concerns with the implantation of the TVT-S and the internal turmoil within the team, Ethicon chose to never update the IFU—indeed Ethicon only had one IFU during the entire time this device was on the market. However, Ethicon chose to remedy the deficiencies of the IFU by offering “procedural pearls,” “tips and tricks” and “cookbooks”—unfortunately, this information was only made available to those surgeons that chose to attend training with Ethicon.

In addition to omitting certain known risks, Ethicon significantly downplayed the risks actually listed in the IFU. This is especially true with respect to erosions. The IFU stated the risk of mesh erosion/extrusion would be immediate or “transitory.” On the topic of erosions, in the Adverse Event/Risks section in the TVT-S IFU, in place from the time of launch until present day, it states:

⁹⁸ ETH.MESH.06051155

⁹⁹ ETH.MESH.00311792 Page 2

¹⁰⁰ ETH.MESH.00312180

Transitory local irritation at the wound site and a transitory foreign body response may occur. This response could result in extrusion, erosion, fistula formation or inflammation.

This language significantly downplays the permanent nature of erosions and suggests to physicians that erosions are a “transitory” or temporary problem. As shown in an email exchange between Ethicon’s Associate Medical Director of Worldwide Customer Quality Meng Chen, M.D., Ph.D. and Bryan Lisa in the Regulatory Affairs Department, it was clear that the adverse events were not “transitory.” Chen wrote, “Pardon me again, from what I see each day, these patient experiences are not ‘transitory’ at all.”¹⁰¹

As previously noted, also noticeably absent from the Adverse Reactions section was dyspareunia and chronic pelvic pain, which were known adverse reactions according to internal Ethicon documents.¹⁰² Dr. David Robinson, Ethicon’s former Medical Director, testified that these were known adverse reactions with the TVT-S.¹⁰³ Though Dr. Robinson was aware that erosion was a possible adverse reaction to the TVT-S and that possible complications associated with the TVT-S included multiple surgeries to treat the resulting erosion, though it was not included in the IFU.¹⁰⁴ In addition, studies revealed that women who were implanted with the TVT-S experienced higher rates of erosion and higher rates of reoperations due to the device’s failure. The IFU does not even address that there is potential difficulty removing the mesh. Thus, despite the known importance of an IFU to physicians, Ethicon provided only vague potential adverse reactions.

Ethicon also had scientific evidence that erosions could occur many years after implantation of the device. In minutes from June 22, 2001 Scientific Advisory Committee on

¹⁰¹ ETH.MESH.04093125 (1/29/09 Email between Meng Chen and Bryan Lisa).

¹⁰² ETH.MESH.04081189-ETH.MESH.04081190 (memo noting Ethicon’s IFU failed to warn its patients of the TVT risks, particularly the dangers of erosion and painful sexual activity).

¹⁰³ David Robinson Dep. at 251:7-12.

¹⁰⁴ Deposition of David Robinson, M.D 7.24.13, 355:16-356:8.

Pelvic Floor Repair, it was a “[c]onsensus: Erosion is a risk. Erosion, possibly an infection response. Typically seen by 3 mos, usually by 6-12 mos. Can present late, 3 years. To vagina-not a good situation. To bladder, urethra or rectum-a very bad situation.”¹⁰⁵ “There have been reports of erosions into the urethra that are not picked up until months even years after the procedure.”¹⁰⁶ In October 2002, Medical Director Dr. Martin Weisberg was involved in an email exchange with European Science Director Axel Arnaud about downplaying risks with respect to erosions. Specifically, Dr. Arnaud suggested to Dr. Weisberg that Ethicon needed “to be more elusive” when discussing potential complications like erosions.¹⁰⁷

According to Medical Director Dr. Martin Weisberg and former Medical Director Dr. David Robinson, Ethicon never disclosed or warned doctors or patients in IFUs or Patient Brochures that the use of TVT-S slings can cause lifelong risk of erosions.¹⁰⁸ Despite the fact Ethicon had scientific feedback from one of its own doctors that experiences were not transitory and that she had concerns about the IFU and the transitory language, Ethicon never informed physicians or disclosed it in its IFU.

In an unpublished summary of the first 12-month human data available on the TVT-S (contained in an internal Clinical Study Report) performed by 6 of the top surgeons in the world who were all Ethicon KOLs (including Vince Lucente, Mickey Karram, Walter Artibani, and Carl Nilsson), there were a total of 51 adverse events reported in 32 out of 72 patients. One of the “safety conclusions” was that “[o]nly 69.4% subjects experienced no major device-related complications.”¹⁰⁹ This human data study went on to note “[o]nly 55% of the women reported no

¹⁰⁵ ETH.MESH.02089392.

¹⁰⁶ ETH.MESH.04099233 (September 24, 2008 email from Melissa Day to Meng Chen and others).

¹⁰⁷ ETH.MESH.03910175-03910177.

¹⁰⁸ Weisberg dep. (8/9/13) 968:2-969:10; Robinson Dep. (9/11/13) 329:12-330:7.

¹⁰⁹ ETH.MESH.02916609.

leak on self-assessment [the *subjective* cure rate].”¹¹⁰ The summary concluded “[i]n the future, well planned randomized studies will have to be conducted in order to discern if the new single-incision procedures can achieve the same level of effectiveness as has been extensively shown with the TVT procedure and (with shorter follow-up) also with the TVT-O procedure. . . . As long as complications occur at the rate seen in this study . . . the single-incision procedure cannot be recommended as a first line treatment for [SUI].”¹¹¹

Ethicon recognized the TVT-S was associated with significantly higher failure rates. Dr. Maree noted in an October 30, 2007 email that the rates of Dr. Lucente’s failure rates of 30% as reported the update were “not at all surprising that we may have similar or higher failure rates here.”¹¹² Dr. Maree recognized that these results were “very different to the QA database numbers sent through from the ‘reported’ complaint rates divided by the USA sales earlier on.” *Id.*

C. ETHICON WITHHELD MATERIAL FACTS ABOUT THE TVT-S

Ethicon should have collected long-term clinical data before selling this completely different TVT product, but they chose not to collect this data. Moreover, Ethicon launched TVT-S worldwide without long-term human use data and without performing any clinical studies, including RCTs as initially promised to their KOLs.¹¹³ They decided against it because board members wanted to accelerate the launch on the product, and performing a clinical study would have caused a delay in the product launch.¹¹⁴ Furthermore, Ethicon decided against these post launch RCTs because of “budget constraints.”¹¹⁵

¹¹⁰ ETH.MESH.02916610.

¹¹¹ ETH.MESH.02916611.

¹¹² ETH.MESH.03845446 Page 1.

¹¹³ ETH.MESH.00134795.

¹¹⁴ Deposition of Patricia Hojnoski April 16, 2013 Page 110 Line 15 to Page 111 Line 9.

¹¹⁵ ETH.MESH.00314794 Page 4.

Since the TVT was first launched, Ethicon has sent materials in various forms to physicians promoting long term follow up data on the original cohort of patients implanted with the TVT from 1995-1996.¹¹⁶ Ethicon continued to cite to this data in all of various TVT product materials. In addition, the materials tout low complication rates related to various adverse reactions, including erosions. These materials include press releases, marketing brochures and email blasts.

The long term data primarily relied on by Ethicon throughout these materials relates to the Ulmsten/Nilsson studies. These studies were originally started by Dr. Ulmsten, the inventor of the TVT, and continued by Dr. Nilsson after Dr. Ulmsten's death. Prior to selling the TVT to Johnson & Johnson, Dr. Ulmsten owned a company called Medscand. Johnson & Johnson hired Dr. Ulmsten and Medscand to conduct studies related to the TVT and its line of products. To this day, Ethicon relies heavily on these studies and uses them in numerous promotional materials despite the fact that Ethicon never disclosed to physicians the potential conflict of interest and inherent bias that exists due to Dr. Ulmsten's relationship with Ethicon and Johnson & Johnson. In addition, Ethicon never disclosed to physicians that the device used in the original Medscand study was different than the TVT-S device. It is important to physicians using the TVT-S that the data in these types of promotional materials is accurate, unbiased and that physicians are informed about any potential conflicts of interest in the data contained within the materials. In other words, physicians rely on Ethicon to provide fair and balanced information and to ensure that physicians have been given all the data and not just the positive press release data.

Despite using the Ulmsten data to promote the TVT-S, Ethicon never disclosed to physicians the bias and inherent conflict of interest related to the Ulmsten data. Specifically, in

¹¹⁶ ETH.MESH.0015598, ETH.MESH.00658058, ETH.MESH.01186068, ETH.MESH.02236784, ETH.MESH.02237103, ETH.MESH.03459211, ETH.MESH.05183409, ETH.MESH.00339437; ETH.MESH.05794787.

its promotional materials, Ethicon (Johnson and Johnson) never informed physicians about its relationship and contracts with Professor Ulmsten and his company Medscand. It is clear from the contracts that the publications and data from Dr. Ulmsten were contracted for hire by Johnson and Johnson International.¹¹⁷

The License and Supply Agreement between Johnson and Johnson International and Medscand (Ulmsten's Company) dated February 13, 1997, states in section 3.6 Milestone Payments:

Johnson and Johnson International (JJI) shall pay shall pay to Medscand the following payments (b). A payment in the amount of \$400,000.00 due on February 28, 1997; provided, however, that in the event that Clinical Trials as specified in Exhibit C have not been completed by such date, then such amount shall not be due until the completion of the Clinical Trials.¹¹⁸

Under Exhibit F, Consulting Agreement with Professor Alf Ivar Ulmsten, section 4 Confidential Information Rights to Inventions and Copyrights (B) it states:

Any copyrightable work whether published or unpublished created by supplier Dr. Ulmsten directly as a result of or during the performance of services herein shall be considered a work made for hire, to the fullest extent permitted by law and all rights, titles and interest herein, including worldwide copyrights shall be the property of the company as the employer and party specially commissioned said work.¹¹⁹

Finally, in Exhibit C, Clinical Trials, it states:

The results of clinical trials will be considered acceptable if, first, they do not differ significantly from the results published in the original article published in the Int. Urogynecol J 1996-7:81-86 by U. Ulmsten, et.al., with regards to the following items: Safety 1.1, preoperative complications 1.2, post-operative complications 1 year from operation 2. Efficacy. Second Long term results over 1 year from operation do not show a deterioration of rates significantly different from those of the standard suburethral slingplasties. It is assumed that from 12 – 60 months a gradual decrease in efficacy of 5% is normal. 3. No significant numbers of unexpected i.e. not addressed in the original article published in the Int. Urogynecol J 1996 7 81-86 by U.Ulmsten et.al. procedure related i.e. not

¹¹⁷ ETH.MESH.08696085-ETH.MESH.086966134.

¹¹⁸ ETH.MESH.08696091.

¹¹⁹ ETH.MESH.0869116

addressed in the review article published in the Int. Urogynecol J 19945: 228-239 by G. N. Ghomiem et.al. complications appear at any time in the postoperative course.¹²⁰

In total, Dr. Ulmsten stood to gain millions of dollars for the 6 papers that he published on the TVT devices. In addition, the results of those studies would be found revenue worthy only if they did not differ from the parameters sent by Johnson & Johnson regarding complications and efficacy. The Ulmsten studies have an inherent conflict of interest and bias as they were “made for hire” and standards were set by Johnson & Johnson. As set forth above, if Dr. Ulmsten did not meet the standards set forth by Johnson & Johnson, he did not receive substantial payments for the “studies.” As a result of this relationship, there is a clear conflict of interest and potential for enormous bias issues.

The conflict of interest and bias created by the relationship between Ethicon and Dr. Ulmsten was acknowledged by Dr. Axel Arnaud, Ethicon’s European Medical Director, in a recent deposition. Specifically, Dr. Arnaud testified that such an agreement like the one discussed above between Dr. Ulmsten and Johnson & Johnson creates a potential conflict of interest.¹²¹ Dr. Arnaud also acknowledged that when Johnson & Johnson enters into this type of agreement with a physician or his company and the study is published, there “certainly” needs to be a disclosure of the relationship.¹²² Additionally, former Ethicon Medical Director, Dr. David Robinson, testified that in his experience working in the industry for medical device manufacturers, it is best that potential biases be disclosed.¹²³ He also testified that if publications from somebody like Ulmsten or Nilsson about safety and efficacy are being

¹²⁰ ETH.MESH.08696132.

¹²¹ Arnaud Dep. (7/20/13) 497:24-501:21, 509:8-17.

¹²² Arnaud Dep. (7/20/13) 514:17-515:1.

¹²³ Robinson Dep. (9/11/13) 214:15-21.

published, it is best if they disclose that they have a financial bias or conflict of interest.¹²⁴ In fact, in an April 2009 email exchange with Medical Director Piet Hinoul about a physician who, like Ulmsten, is a consultant and inventor for competitor Boston Scientific, Dr. Robinson states that that situation presents “enormous bias issues.”¹²⁵ Despite two of its medical directors testifying that the relationship between Ulmsten carried over to Nilsson presents a conflict of interest and bias, Ethicon has never disclosed this information in its promotional pieces. This is information physicians and patients have a right to know so that a proper informed decision regarding the value of the data in the studies and the use of the product can be made.

Aside from never disclosing to physicians the underlying conflict of interest and bias of the Ulmsten studies in its promotional pieces, Ethicon also never informed them about other problems with the data, including incomplete data on the original cohort, data incorrectly reported and erosion rates underreported. In the original 510(k) submission for TVT Classic, Ethicon used Medscand data from the Scandinavian Multicenter Study.¹²⁶ The report shows that the 12 month follow-up was obtained for 90 of the original 131 patients, without explanation of why there was a loss of 41 patients from the study. The study also describes a complication of wound infection: “while the vaginal infection required surgical intervention with resection of exposed mesh.”¹²⁷ This represents a vaginal mesh erosion/extrusion/exposure and needs to be reported as such. However, when the paper was published (Ulmsten, *Int Urogynecol J* 1998), the paper states that there was no defect healing and no tape rejections. It further misrepresents the outcome for this patient as “[t]he patient with the wound infection had vaginal atrophy. After

¹²⁴ Robinson Dep. (9/11/12) 215:8-13.

¹²⁵ ETH.MESH.03259439; Robinson Dep. (9/11/13) 219:6-220:10.

¹²⁶ ETH.MESH 00371587.

¹²⁷ *Id.*

minimal vaginal wall resection and effective local estrogen treatment she healed without further intervention. There was no tape rejection.” *Id.*

If Ulmsten had reported a mesh erosion/extrusion/exposure with mesh excision in his study, it would not have been acceptable under Exhibit C of his consulting contract for payment of the \$400,000.¹²⁸ This demonstrates that the results of this paper were potentially biased by the payment Ulmsten would receive for favorable data and should discount the data. At the very least, Ethicon should have informed physicians about the relationship between Ethicon and the Ulmsten studies.

Many of the marketing brochures tout the “[t]he urethral erosion rate less than or equal to that of traditional slings; no reported urethral erosions in 10 studies of 50+ patients.”¹²⁹ The reference used for the first part of this statement is from Dr. Gary Leach who looked at traditional sling procedures done before 1993, when traditional slings were performed at the bladder neck and purposely placed under tension to treat severe stress urinary incontinence from intrinsic sphincter deficiency (particularly among Urogynecologists).

The second part of this statement regarding “no urethral erosions” is incorrect. In published studies, Dr. Karram found one case of urethral erosion in his study of 350 Gynecare TVTs performed (Karram Obstet Gynecol 2003) and Hammad found nine cases of urethral erosion in his study (Hammad Eur Urol 2005).¹³⁰ His study followed the complications of 1459 patients, 993 of whom had Gynecare TVT, while the remainder had SPARC procedures. While the authors do not break down the incidence of urethral erosion by product, it is exceedingly unlikely that all erosions happen in the SPARC group. The statement regarding “no urethral

¹²⁸ ETH.MESH 08696132.

¹²⁹ ETH.MESH 00339439.

¹³⁰ Karram, M.M., et al., *Complications and untoward effects of the tension-free vaginal tape procedure*, Ob & Gyn 2003, 101:929-32.

erosions” also did not include de Tayrac's 2003 paper of 61 patients (31 TVTs) which showed a 3% urethral erosion rate.¹³¹ Dr. Shlomo Raz described a study of 26 patients who presented with voiding dysfunction, including symptoms of severe urethral, pelvic and genital pain, urinary retention, recurrent UTIs, de-novo urgency with urge incontinence found to have mesh from a sling procedure in the bladder or urethra.¹³² Their patients were found to have been treated conservatively with anticholinergic medication. They conclude that “dysfunctional voiding symptoms after sling procedure should elicit a high degree of suspicion if pharmacotherapy is not successful in alleviating symptoms...Cystoscopy should be considered if the patient remains symptomatic despite pharmacotherapy.”

In one of the Nilsson studies, Dr. Nilsson describes four patients on “anticholinergics” (Int Urogynecol J 2008 Table 3). They conclude: “[i]t is also encouraging to see that no late adverse effects of the polypropylene tape material was found and that erosion of the tape into adjacent tissue did not occur.” However, this statement cannot be made for 4 patients who are on pharmacotherapy without a cystoscopy, which was not performed in the 11 year follow-up study. Dr. Raz’s review of the literature found multiple cases of urethral erosions in a large series with TVT.¹³³ There have also been multiple case reports attesting to the fact that urethral erosion does occur specifically with Gynecare TVT products.¹³⁴ To imply that urethral erosion does not occur is not giving physicians fair and balanced information about the true incidence of urethral erosions with TVT products.

¹³¹ de Tayrac, R., et al, *A prospective randomized trial comparing tension-free vaginal tape for surgical treatment of stress urinary incontinence*, Am J Obstet Gynecol 2004, 190:602-8.

¹³² Deng D.Y., et al., *Presentation and management of major complications of midurethral slings: Are complications under reported*, Neurourology Urodynamics 2007, 26:46-52.

¹³³ Karraam 2003, Hammad 2005.

¹³⁴ Sweat, S., et al., *Polypropylene Mesh Tape for Stress Urinary Incontinence: Complication of Urethral Erosion and Outlet Obstruction*, J Urology 2002, 168:144-146; Gerstenbluth, R.E., et al, *Simultaneous Urethral Erosion of Tension-Free Vaginal Tape and Woven Polyester Pubovaginal Sling*, J Urol. 2003, (2 Pt 1) 170:525-6; Vassallo, B.J., et al., *Management of iatrogenic Vaginal Constriction*, Am J Obstet Gynecol 2003, 102(3):512-20; Haferkamp, A., et al., *Urethral Erosion of Tension-Free Vaginal Tape*, J Urol 2002, 167(1): 250.

Later, Nilsson published the 5 year follow-up of this cohort.¹³⁵ He describes the cohort: “[A] prospective open multicenter trial was conducted in the Nordic countries at the beginning of 1995. The short-term results were published in 1998.” This implies that these are the same patients as published in 1998. It is interesting or an incredible coincidence that the exact number of patients receiving 12 months of follow-up in the Medscand publication, ninety (90) patients was the exact number being described in the 5 year study. There is again no mention of the outcome of the other 41 patients from the original cohort. Another interesting detail in the 5 year study is that the original number of centers used for the study [six centers] was now down to 3, again without explanation. The 5 year report does describe the original patient with the wound infection but again fails to mention she had mesh excised, “1 case (1.1%) of infection of operating site was observed.”

In 2006, Dr. Nilsson published a different study on the long term outcome of patients with TVT.¹³⁶ He describes his new patient population: “A multi-center study comprising only carefully selected primary cases revealed a promising cure rate of 85% after 5 years (referenced his 5 year study) and 81% at 7 years.”¹³⁷ These two papers are the subject of many press releases and marketing brochures, but they never described that these were carefully selected patients. “To our knowledge, the long-term effect and effectiveness of the TVT procedure has not yet been studied in an unselected patient group. We earlier reported 16-month follow-up results of a general patient group referred to a tertiary medical unit and comprising primary, recurrent, mixed, and low pressure urethra cases. In the present study, we report the long-term results in the same above-mentioned group.” They describe a 3.1% mesh “visualized” rate, half

¹³⁵ Ulmsten data; Nilsson, *Int Urogynecol J* 2001.

¹³⁶ Kuuva, N., *et al.*, *Long-term results of the tension-free vaginal tape operation in an unselected group of 129 stress incontinent women*, *Acta Obstetricia Gynecologica Scandinavica* 2006, 85:4 482-87.

¹³⁷ Nilsson, *Obstet Gynecol* 2004.

of which needed surgical resection. These results, more representative of what one would see in a normal practice, is never mentioned in press releases or marketing documents.

Conversely, when Ethicon receives adverse information, it does not make it into the promotional pieces. Dr. AC Wang's abstract, "Tension-Free Vaginal Tape (TVT) for Urinary Stress Incontinence - A Preliminary Report" was used in the original 510k submission in October of 1997 as support for FDA clearance of the TVT.¹³⁸ However, when Dr. Wang reported that he had 25 cases of "failure of vaginal healing considered by him to be potential tape rejection...in each case the revision failed within 2 weeks, requiring further surgery to excise mesh and repair the vaginal wound," this important information never made it into the marketing materials or press releases.¹³⁹

As an alternative to RCTs initially promised to certain KOLs (documents reflect they would not have endorsed the TVT-S otherwise), Ethicon started "TVT World" as a long-term clinical and patient reported outcomes on the use of the Gynecare TVT systems for SUI.¹⁴⁰ The first patient enrolled on February 16, 2007. However, because the TVT-S was losing market share and failing to meet expectations among surgeons, Ethicon discontinued the TVT World registry in March of 2009¹⁴¹ stating that they "had sufficient data generated from 1,367 patients as of March 11, 2009 already enrolled . . . although we are still some way off the initial target of 5,000 patients."¹⁴² TVT World closed 3,500 patients short of Ethicon's initial "class" goal because they determined that the TVT-S was not commercially viable.

Two KOL professors for Ethicon, Nilsson and Artibani, expressed worries about Ethicon "launching TVT Secur with no clinical data (other than the 50 patients, 5 weeks to follow

¹³⁸ ETH.MESH.00371551.

¹³⁹ ETH.MESH.00409675.

¹⁴⁰ ETH.MESH.00134794 Slide 6.

¹⁴¹ ETH.MESH.00134794 Slides 13 and 14.

¹⁴² ETH.MESH.03208592.

up).”¹⁴³ Professor Artibani was “surprised Ethicon did not learn the lesson from the launch of a prior product, MoniTorr...” when discussing the lack of clinical data. Harel Gadot, Ethicon’s European Marketing Manager, then strongly recommended that Ethicon “find a way not to cancel completely the proposed RCT” because Ethicon assured their KOLs that they would conduct RCTs so that they would commit to being preceptors for the device. Because of this, Mr. Gadot encouraged Ethicon to protect Johnson & Johnson’s reputation and not to cancel the RCT.¹⁴⁴ However, Ethicon elected to cancel the RCT anyway.

Carl Nilsson, the same Ethicon KOL who co-authored the 3, 5, 7, and 17-year studies on the TVT-Retropubic and was going to be Ethicon’s “ambassador” for the TVT-S, wrote an article in 2015 related to the need for clinical studies on new medical devices.¹⁴⁵ While Dr. Nilsson did not specifically call out the TVT-S as being flawed, given the internal Ethicon documentation substantiating his criticisms of Ethicon with the device, it is particularly telling:

Recent history includes the launch and withdrawal of many modifications and copies of the TVT procedure, which shows that any variation of a procedure needs its own thorough clinical testing before it can be accepted for common use. The surprisingly high rates of complications such as bladder perforation and post-operative voiding problems seen in more recent reports compared with the rates seen in the initial ones from the Nordic countries emphasizes the need for proper training and adherence to the standardized performance of the operation in order to avoid complications and poorer performance. It is a waste of both public and private resources to launch poorly documented new treatment concepts and it is especially wrong for the women suffering from [SUI] to become the subjects of experimental efforts without ethical approval and written informed consent.¹⁴⁶

The long-term follow-up data (Ulmsten/Nilsson data) used by Ethicon to promote the lack of risk of TVT-S is spurious at best. We have incomplete data on the original cohort, data that is falsely reported, original sites that were excluded without explanation and a lead

¹⁴³ ETH.MESH.03172197.

¹⁴⁴ *Id.*

¹⁴⁵ Nilsson, *Creating a gold standard surgical procedure: the development and implantation of TVT*, Int. Urogynecol. J. (2015) 26:467-269.

¹⁴⁶ *Id.*

investigator who had a significant relationship and financial incentive to reach certain results with the data. This is the same data which is now used repeatedly in promotional and marketing materials sent to physicians.

I have reviewed over a thousand papers discussing, among other things, surgical methods, surgical techniques, complications, and summaries of clinical testing and trials on TVM products, including the TVT-S. I previously served on a medical advisory board where I helped design a RCT for a device used for the treatment of SUI. I have also acted as an investigator in conducting RCTs on drug treatments for urinary incontinence and phase 1 Federal trials on medical devices to seek clearance for over the counter use. Additionally, I have conducted RCTs on amnio-infusion and contraction stress tests during labor. I agree with Dr. Nilsson, along with Ethicon's other KOLs who advocated for Ethicon to conduct clinical testing prior to the commercialization of the TVT-S. Given both the completely different characteristics associated with this device and the unique surgical technique used to implant the TVT-S, for this product to be properly evaluated, the TVT-S and surgical procedures (associated with both the "U" and "hammock" placement) should have been used in short and long-term clinical studies to determine intraoperative/postoperative morbidity and surgical cure rates. In this respect, a carefully selected patient population with an extensive informed consent process designed to clearly notify participants that the use of the TVT-S was purely experimental in such studies would have been appropriate. If any such RCTs had been conducted, the various implantation issues and other flaws identified herein with the TVT-S would have been studied and identified prior to being permanently implanted into women's bodies. Instead, the TVT-S was introduced into the market place and sold as an "easy-fix" procedure to obstetric/gynecologists across the country, when only highly skilled pelvic floor surgeons should have implanted the TVT-S.

D. THE DESIGN OF THE TVT-S WAS DEFECTIVE.

Although Ethicon utilized the TVT and TVT-O as predicate devices in its TVT-S 510(k) application to the FDA, these devices are completely different from the TVT-S. For example, the TVT-S' inserters had never been used before¹⁴⁷ and the length of the tape and the mechanism of insertion are completely different. One of Ethicon's KOLs commented to an Ethicon employee in November 2007 that the "TVT S is so 'utterly different to the other TVTs that it probably shouldn't be called a TVT' and the speed to market and breadth of the launch did not take this into account."¹⁴⁸ Ethicon's World Wide Medical Director in 2007, Dr. David Robinson, recognized that the TVT-S was "a sling 'unto itself' as far as techniques go."¹⁴⁹

The insertion mechanism was known to be difficult because of the complications with the dislodging of the anchoring of the TVT-S. There were also difficulties with the tape. It was very difficult to properly tension the device, and the need for significantly greater tension was never communicated to surgeons whose comments reflect the degree of tension. Thus, the low tension was proving quite difficult for surgeons than they were accustomed to seeing in the TVT or TVT-O, which resulted in lower cure rates.

Ethicon knew that the incision size was not accurate in the IFU and should have been wider. Ethicon also knew that the smaller incision size reflected in the IFU caused a greater risk of mesh extrusion/erosion to the patient. Internal Ethicon documents reflect there was no agreement on the amount of dissection or depth of the surgical incision with the TVT-S. The IFU states that the incision size should be 1.0-1.5 cm.¹⁵⁰ However, the "the cookbook,"¹⁵¹

¹⁴⁷ Deposition of Dr. David Robinson, 7.24.13 Page 116 Lines 5-22.

¹⁴⁸ ETH.MESH.00327062.

¹⁴⁹ ETH.MESH.00642328.

¹⁵⁰ ETH.MESH.02340568-ETH.MESH.02340590.

¹⁵¹ ETH.MESH.03752501- ETH.MESH.03752506.

“procedural pearls,”¹⁵² and internal e-mails reflect the need for a larger incision size. On January 20, 2007,¹⁵³ Menachem Neuman (well-renowned urogynecologist from Israel and TVT-S trainer for Ethicon) wrote an email in response to Isabelle Perez’s (Professional Education Co-Coordinator Ethicon France) request to share “success stories” from Neuman’s recent TVT-S training visits to Portugal and other European countries during the last few months of 2006 and early January of 2007. Dr. Neuman related the following:

- It would be necessary for a surgeon in training to undergo 5 training operations with Neuman to become a “flying surgeon” (Preceptor). Thereafter, the “flying surgeon” would need an additional 20 to 30 operations to form the “inner-country” pyramid of homeland trainers.
- Surgeons who are more familiar with TVT-O will require more training for the TVT-S in order to overcome the “dragged bad habits” from the former operations to the new one. There are special differences between the TVT-O and TVT-S and those should be addressed to and respected if high cure rates and low complication rates are desired.¹⁵⁴

In this email, Dr. Neuman attached a copy of his TVT-S Preceding Steps,¹⁵⁵ which do not parallel the TVT-S’ IFU. But, Ethicon upper management was aware of this information because Dr. Neuman’s email was forwarded to David Robinson, Kevin Mahar, Bob Roda (Ethicon Group Marketing Director Worldwide), and Dharini Amin (Ethicon Product Director) on January 23, 2007.

In February 2007, Dr. Robinson emailed a copy of an abstract prepared by Dr. Neuman to Judith Gauld.¹⁵⁶ The abstract evaluated Dr. Neuman’s “learning curve” with his first 100 patients implanted with the TVT-S. The abstract concluded “[t]he trainer’s learning curve was reasonable and yielded some insights, among them are the necessity of meticulous and proper dissection prior to tape placing and the need of applying some minimal extra tension on the

¹⁵² ETH.MESH.07039973-ETH.MESH.07039975 (stating that the incision size should be 1.2-1.5 cm).

¹⁵³ ETH.MESH.02320485-ETH.MESH.02320489.

¹⁵⁴ ETH.MESH.02320486.

¹⁵⁵ ETH.MESH.02320488.

¹⁵⁶ ETH.MESH.01782942

mesh.”¹⁵⁷ It noted that the TVT-S device “*being relatively slightly more rigid than the previous ones, tends to protrude the vaginal mucosa on the post-operative course*. This was addressed by abounding the rapidly absorbed vaginal stitches and by mucosal undermining in order to permit the tape to sink deeper, away from the vaginal mucosa. The inserters, being more than twice wider than the TVT and TVTO needles, necessitates larger tunnel; 12 mm’s at least, in order to permit smooth passage of the tape and inserter and avoid mucosal placcation which might lead to vaginal wall penetration.”¹⁵⁸ In 2011, Dr. Neuman published his findings that the TVT-S caused significantly more dyspareunia than the TVT-O due the stiffness/rigidity of the mesh.¹⁵⁹

On May 16, 2007, Harel Gadot wrote to several Ethicon employees, including Dr. Robinson, saying one of the main issues to be addressed in Ethicon’s new procedural steps CD should be the “undermining” (as Dr. Neuman called it) to allow the mesh to lay flat under the urethra. All the surgeons felt that was a very important step that they were missing.¹⁶⁰ In reply to the email, Amin replied that “[a]ny changes will delay the project by 1 month and the US needs this soon before AMS launches [their mini-sling] at the end of June. If we need to change the video we can open another project for the European team to add additional footage to the current video.”¹⁶¹ In another reply, Amin wrote, “On the 1st page we added comment ‘around 1.5 cm incision and of full thickness, to allow mesh to law flat underneath urethra. This may

¹⁵⁷ ETH.MESH.01782949

¹⁵⁸ ETH.MESH.01782956.

¹⁵⁹ Neuman M. Transobturator vs. Single-Incision Suburethral Mini-slings for Treatment of Female Stress Urinary Incontinence: Early Postoperative Pain and 3-year Follow Up. *J Min. Invas. Gynecol* 2011; 772 (dyspareunia rate over 162 patients with TVT-S 7.9% vs. TVT-O 0%, explaining dyspareunia due to rigidity and reduced flexibility of mesh with TVT-S because it was laser cut, which tends to result in stiff tape edges).

¹⁶⁰ ETH.MESH.03922436.

¹⁶¹ ETH.MESH.03922435.

reduce risk of incision disruption and mesh exposure.”¹⁶² She also noted that “we cannot put pearls in the technical guide which is used to explain the IFU in detail.”¹⁶³

On July 26, 2007, Greg Prine (Regional Business Director - Sales) and Selena Lessa (Division Manager – Sales) received the Key Technical Points showing that the vaginal incision “should be made **slightly larger** than with conventional slings (**closer to 1.5 cm**) and of full thickness, to allow mesh to lie flat underneath urethra. This may reduce risk of incision disruption and mesh exposure.”¹⁶⁴ In August 2007, Dr. Jaime Sepulveda, another Ethicon KOL, sent an e-mail with the summary of the “critical steps” session regarding the placement of the TVT-S. This email focused on the device placement, tensioning, inserter removal, and closure. On August 28, 2007, Mr. Prine received a copy of Dr. Sepulveda’s summary of the Critical Steps session that was presented at an August 24th Ethicon meeting *with preceptors* (these are surgeons who are paid by Ethicon to train other surgeons on the TVT-S), where he wrote that “[a]n incision of 1.5 – 2.0 cm . . . was required.”¹⁶⁵ In 2009, Dr. Sepulveda ran a training session where he noted that a vaginal incision of +/- 2 cm was *necessary* for the TVT-S.¹⁶⁶

This disagreement over the incision size for the TVT-S was known and identified by Ethicon during the early stages of the TVT-S being on the market. Yet even though the IFU was the controlling document for surgeries, these subsequent “cookbooks” and “pearls” were only distributed to doctors if the representatives received complaints or were high volume users.¹⁶⁷

The TVT-S was also more prone to failing and maintaining the angle of correction at the urethra for control of SUI. The tensioning and fixation problems were known to Ethicon¹⁶⁸ as

¹⁶² ETH.MESH.03922434.

¹⁶³ ETH.MESH. 03922435.

¹⁶⁴ ETH.MESH.17666960-ETH.MESH.17666969.

¹⁶⁵ ETH.MESH.10226089.

¹⁶⁶ ETH.MESH.02596703.

¹⁶⁷ ETH.MESH.03752501-ETH.MESH.03752506.

¹⁶⁸ ETH.MESH.00329316, ETH.MESH.05473738, ETH.MESH.05530459, ETH.MESH.05530464, ETH.MESH.

they saw inferior TVT-S cure rates as compared to the TVT and TVT-O.¹⁶⁹ Ethisorb may have also been a contributing factor to the fixation concern (it had never been studied for mesh fixation in the human pelvic floor region). One study showing a 42% failure rate with the TVT-S concluded that “[O]ur experience shows that despite its good short-term efficacy, TVT-Secur is associated with a high recurrence rate of SUI. Therefore, TVT-Secur does not seem appropriate for SUI first-line management in women.”¹⁷⁰ In fact, Ethicon’s internal documents showed that surgeons in 2007 were experiencing “high ‘failure’ rates across multiple centers.”¹⁷¹

Dr. Robinson was aware that possible complications associated with the TVT-S included multiple surgeries to treat the resulting erosion.¹⁷² Studies revealed that women who received the TVT-S experienced higher rates of erosion and higher rates of reoperations because of the various defects noted herein. One study prepared by Lekha S. Hota, M.D., an Ethicon KOL, stated that “there also was an increased incidence of mesh exposure in the TVT-S group. Although the etiology of this complication is unclear, we theorize that the sharper edges of the TVT-S introducer potentially create more trauma to the vaginal epithelium and may result in high erosion rates.”¹⁷³ Ethicon never investigated the possibility that its product’s sharper edges might subject patients to greater tissue trauma, potentially resulting in erosions.

Despite Ethicon’s knowledge of these various defects, it kept the TVT-S on the market. Ethicon’s Quality Board conducted an analysis due to complaints in Australia in 2007. At this time, they were told that the two most significant US complaints were that the implant pulls out

05530469.

¹⁶⁹ Hota L. TVT-Secur (Hammock) Versus TVT-Obturator: A Randomized Trial of Suburethral Sling Operative Procedures. *Female Pelvic Med Reconstr Surg*. 2012, 18(1): 41-45 (47% cure rate with TVT-S and 91% cure rate with TVT-O); Maslow K, Gupta C. Randomized clinical trial comparing TVT Secur system and trans vaginal obturator tape for the surgical management of stress urinary incontinence. *Int Urogynecol J* (2014) 25:909–914 (63% cure rate with TVT-S and 86% cure rate with TVT-O).

¹⁷⁰ Cornu JN, Midterm prospective evaluation of TVT-Secur reveals high failure rate, *Eur Urol*. 2010; 58(1):157-61.

¹⁷¹ ETH.MESH.00642330- ETH.MESH.00642331.

¹⁷² Depo of David Robinson, M.D 7.24.13 Page 355 Line 16 – Page 356 Line 8.

¹⁷³ ETH.MESH.04474756 – ETH.MESH.04474760.

with the inserter and that the inserter itself was difficult to remove.¹⁷⁴ A November 6, 2006 email from Mark Yale to Medical Director David Robinson¹⁷⁵ and others reveals an issue with the TVT-S arising shortly after the launch of the product (June 2006). The specific issue is regarding the withdrawal of device itself with inserter and anecdotal concerns of a high rate of occurrence with injuries related to device not coming off inserter during removal causing the device to be moved or pulled out along with inserter.

In a May 17, 2007 presentation to Ethicon employees by Dr. Axel Arnaud (Medical Affairs Director of Ethicon, Europe Middle East and Africa), he noted that “[s]ome key experts and non-experts are disappointed,” and “[k]ey experts are abandoning the procedure.” He went on to state that the “advantages of conventional TVTs are insufficient for accepting more failures.”¹⁷⁶ On October 25, 2007, Dr. Aran Maree (Medical Director of Australia and New Zealand) attributed the failures to the product having been “launched as a substitute for TVT-O without enough clinical data to justify the roll-out,” and that the original training program did not result in “competency in device insertion.”¹⁷⁷ Furthermore, on November 2, 2007, Dr. Maree advised Catherine V. Beath (WW VP of Quality Assurance) that three seasoned surgeons experienced multiple 6-week failure rates—this included Prof. Malcolm Frazer, a surgeon who had performed about 700 TVT cases over the years, who experienced 13 failures out of 20 surgeries (a 65% failure rate).¹⁷⁸ All of these surgeons determined that these failure rates that they were experiencing with the TVT-S were above their previous failure rates with the TVT and TVT-O.

¹⁷⁴ ETH.MESH.06051286 Page 5 and 25.

¹⁷⁵ ETH.MESH.0329316.

¹⁷⁶ ETH.MESH.00572598

¹⁷⁷ *Id.*

¹⁷⁸ ETH.MESH.00312179-182

In 2014, the Cochrane Collaboration analyzed various single-incision operations for urinary incontinence in women by interpreting the results of a number of RCTs and quasi-RCTs.¹⁷⁹ Though there was no ultimate conclusion on the efficacy or safety of any SIS other than the TVT-S, SISs were noted to result in higher incontinence rates compared with inside-out transobturator slings (30% vs 11%; RR 2.55, 95% CI 1.93 to 3.36). The adverse event profile was also noted to be significantly worse, consisting of higher rates of operative blood loss, vaginal mesh exposure, and bladder/urethral erosion. These findings were mostly derived from trials involving the TVT-S. The authors concluded that the TVT-S was “considerably inferior to retropubic and inside-out transobturator slings” and was “inferior to standard mid-urethral slings for the treatment of women with stress incontinence.” In fact, a systematic review of RCTs comparing single-incision mini-slings to standard midurethral slings needed to exclude data on the TVT-S in order to show there were no significant differences in efficacy or complication rates between mini-slings and midurethral slings.¹⁸⁰

E. POST-MARKETING ADVERSE EVENTS

Ethicon did not actively try to determine how many patients were hurt by its devices, including the TVT-S, or how severely they were hurt. Instead, Ethicon had a “passive” system of measuring how many and what type of adverse events the TVT-S was causing. Ethicon’s Director of Post-Marketing Surveillance testified that this type of passive collecting of reports understates how many people are actually being hurt by its devices:

¹⁷⁹ Despite having already been withdrawn from clinical use at the time of the study, the report included the TVT-Secur “so that level 1a data” would be “available in the literature to confirm its lack of efficacy.” Nambiar A, Single-incision sling operations for urinary incontinence in women; *Cochrane Database of Systematic Reviews* 2014, Issue 6.

¹⁸⁰ Mostafa A, Single-Incision Mini-Slings Versus Standard Midurethral Slings in Surgical Management of Female Stress Urinary Incontinence: An Updated Systematic Review and Meta-analysis of Effectiveness and Complications; *European Urology*, 2014; 402-427 (“This meta-analysis shows that, excluding TVT-Secur, there was no evidence of significant differences in patient-reported and objective cure between currently used SIMS and SMUS at midterm follow-up while associated with more favorable recovery time.”).

THE WITNESS: So we -- from a reactive perspective for complaints, we can only process the complaints that are reported to us, so -- and as we discussed earlier, they come from many different avenues; but again, they're reactive in nature, which means we are processing what is given to us or reported to us.

Q. You understand that spontaneous adverse event reporting, such as your department collects and analyzes, has been demonstrated to substantially under quantify the real complications in the world?

A. So the adverse events that are reported to us, complications, complaints that are reported to us, are a subset of the events, complaints, complications that occur in the field.¹⁸¹

In fact, Ethicon employees ensured that they would not “actively” collect any complaints.

When discussing how to perform a marketing survey with a number of physicians, Dan Smith wanted to ensure Ethicon people did not ask physicians questions that might “collect” a complaint:

Just a thought with regard to us collecting information. Paul, what was the ruling from our compliance group regarding us asking questions/collecting data, did we have to log issues as complaints???? et cetera. If so, we should do this in a manner that avoids this issue.¹⁸²

Dr. David Robinson, Ethicon’s Medical Director, noted a reason that Ethicon might not want to actively collect adverse events about its products: “[I]f this starts getting reported, it is going to scare the daylights out of docs.”¹⁸³

Even though Ethicon limited its “surveillance” to passively collecting complaints, it did not do this well. For example, Mark Yale, the head of Ethicon’s Worldwide Customer Quality team testified that all Ethicon employees had a legal duty to report any and all complaints to the Company about which they became aware.¹⁸⁴ When shown documentation, Yale admitted that

¹⁸¹ Lamont Dep. (4/4/13) 389:25-390:23; Yale Dep. (8/7/13) 126:20-127:7 (“So you would agree that generally in a passive complaint collection, which is what Ethicon had prior to this discussion about the registry, for example, in a passive collection, that it is well known and well recognized that adverse events are underreported. Correct? THE WITNESS: In general, the basic understanding in the world of complaints and adverse events is that you do not get 100 percent reporting, that, you know, it is not the perfect collection model to gather. So, yes, they are, in some manner, underreported.”).

¹⁸² ETH.MESH.01811770.

¹⁸³ ETH.MESH.00756984 (Email from David Robinson, M.D. to Giselle Bonet and Marty Weisberg).

¹⁸⁴ Yale Dep. (8-7-2013) 140:12 to 140:16.

this collection system was flawed. For example, employees in a US call center failed to report complaints,¹⁸⁵ employees in Eastern Europe did not know they were required to inform the Company of complaints and adverse events,¹⁸⁶ one Portuguese employee testified that he would not have reported the complaint, but someone had already informed the regulatory authorities:

Q. So Francisco in Portugal working for Johnson & Johnson Medical says he wouldn't have reported this to you, this complication, except for the fact that somebody reported it to their regulatory authorities. Right?

A. That's what he wrote. Correct.¹⁸⁷

This line of questioning led to a consistent theme about adverse events and complications tracking at Ethicon – you don't know what you don't know. Yale testified:

Q. So as you sit here today, you have no idea how many other complaints didn't make it here from Portugal, because Francisco Noronha from Johnson & Johnson decided that if it wasn't reported to his regulatory agency, he's not going to tell you about it. Right?

THE WITNESS: I don't know what I don't know.¹⁸⁸

When David Menneret, an employee of the mesh manufacturer at Ethicon SARL received a complaint about mesh being frayed (a significant issue as discussed above) he was unsure whether to report it as a “complaint” into the Ethicon complaint tracking system. He wrote:

Please see attached below a letter...regarding Mesh fraying. I don't know exactly who should be informed of this kind of customer feeling so feel free to forward to anyone concerned. Do you think this should be entered as a complaint in the system?¹⁸⁹ Again, Yale testified that he could not know how many complaints went to the manufacturer about the fraying from the manufacturing process that ultimately were not reported to Ethicon's complaint tracking system.

He testified as follows:

¹⁸⁵ Yale Dep. (8-7-2013) 145:12 to 145:15.

¹⁸⁶ Yale Dep. (8-7-2013) 155:21 to 155:25.

¹⁸⁷ Yale Dep. (8-7-2013) 159:5 to 159:10.

¹⁸⁸ Yale Dep. (8-7-2013) 160:16 to 160:24.

¹⁸⁹ ETH.MESH.01814252.

Q. You don't know how many times Menneret didn't report a complaint either. Right? You don't know what you don't know. Right?

THE WITNESS: As I said before, I do not know what I do not know....¹⁹⁰

Prior to March of 2006, Ethicon did not even have a formal procedure in place to capture adverse events from its own clinical trials. Therefore, they had no idea how many adverse events occurred but were not reported from those trials.¹⁹¹

In addition to the marketing materials, Ethicon also provided physicians with “Complications Statements” during training or upon request. These “Complication Statements” relied upon the information captured in Ethicon’s complaint system – the same system described above. Accordingly, the capture of information for these statements was already severely compromised. However, even for those events Ethicon did capture, the reporting of these events in the Complications Statements was completely misleading.

Joseph Scavona, a complaint analyst, was responsible for creating one of these Complications Statements that was provided to physicians. He described how he created the statement and how, if a woman had multiple injuries, he only listed one injury on the chart. He wrote:

[S]ome complaints could be described with multiple main & sub categories, but each complaint was only labeled with one of these categories (e.g. patient had pain, bleeding, hematoma, exposure, and dyspareunia thus complaint was coded only “mesh exposure”).¹⁹²

This completely misrepresented the actual harms data. Moreover, the person making these decisions, Scavona, was not a medical doctor. He recognized these limitations and requested that medical review the complications data, but it did not occur.¹⁹³ Instead, physicians

¹⁹⁰ Yale Dep. (8-7-2013) 168:24 to 169:12.

¹⁹¹ Yale Dep. (8-7-2013) 194:22 to 195:7.

¹⁹² ETH.MESH.02122904 (Ex. 970) (Email from Joseph Scavona to others re “TVT Complications Statement 2008”). Complications Statement attached at ETH.MESH.00007091 at 2 (Ex. T-970).

¹⁹³ *Id.*

were provided with misleading, inaccurate and incomplete information in the Complications Statements.¹⁹⁴

In my opinion Ethicon's collection and reporting of adverse events and complications to physicians and patients was incomplete, inaccurate and misleading. As manufacturers are the only entities with access to complaint information, physicians and patients must rely upon them to provide timely, accurate and complete information. Ethicon failed to do so. Without accurate information, physicians could not and cannot obtain informed consent from their patients, nor can patients give informed consent. Ethicon's complaint collecting and reporting system made this impossible.

E. ETHICON'S FAILURE TO DISCLOSE THE CONTENTS OF THE MSDS

According to Ethicon Medical Director, Dr. Martin Weisberg, a Material Safety Data Sheet (MSDS) is "a document that discusses the product, the composition, any potential hazards from it . . . Generally, the safety particular of products."¹⁹⁵ As it relates to polypropylene, I have reviewed several MSDSs for polypropylene resin used to manufacturer meshes used in various pelvic floor meshes. All of the MSDSs discussed below are available to the public.

Sunoco, the manufacturer for the polypropylene resin used to manufacture Ethicon's pelvic floor products lists the possibility that polypropylene mesh can cause tumors or cancer.

This is documented by the Sunoco MSDS¹⁹⁶ from April 13, 2005 which states in relevant part:

OTHER INFORMATION

Follow all MSDS/label precautions even after container is emptied because it may retain product residue.

COMPONENT TOXICITY: Polypropylene has been tested in laboratory rats by subcutaneous implantation of discs or powder. Local sarcomas were induced at the implantation site. No epidemiological studies or case report suggest any

¹⁹⁴ Yale Dep. (8-8-2013) 294 to 300.

¹⁹⁵ Weisberg Dep. (8/9/13) 909:2-9.

¹⁹⁶ ETH.MESH.02026591 at 6591-6595.

chronic health hazard from long term exposure of polypropylene decomposition products below the irritation level. (OARC, 19, 128).¹⁹⁷

Dr. Martin Weisberg, Ethicon Medical Director, is not only familiar with this MSDS, he also has personal experience with it. Dr. Weisberg agrees that the manufacturer of Ethicon's mesh did a study by implanting it under the skin of rats and it did in fact induce sarcomas.¹⁹⁸ Dr. Weisberg also agrees "if there was evidence of cancer-causing abilities of polypropylene . . . a reasonable doctor would want to know."¹⁹⁹ And, despite evidence to the contrary in the above MSDS for the resin used to make the polypropylene mesh for TVT, he is not aware of any instance when Ethicon "disclosed to any doctor that there's any evidence that the use of polypropylene mesh might induce sarcomas in its patients."²⁰⁰

Dr. David Robinson, a former Ethicon Medical Director, testified he was unaware of Ethicon ever performing any studies or research to determine whether polypropylene could cause cancer in the long term.²⁰¹ In addition, he testified that Ethicon never disclosed "the potential that polypropylene in the product could be cancer causing."²⁰² Dr. Robinson also testified that it would be reasonable for physicians to want to know about polypropylene possibly causing cancer.²⁰³

Another MSDS from Chevron Phillips,²⁰⁴ a manufacturer of polypropylene resin states:

MEDICAL APPLICATION CAUTION: Do not use this Chevron Phillips Chemical Company LP material in medical applications involving permanent implantation in the human body or permanent contact with internal body fluids or tissues.

Do not use this Chevron Phillips Chemical Company LP material in medical applications involving brief or temporary implantation in the human body or

¹⁹⁷ *Id.* at 02026595.

¹⁹⁸ Weisberg Dep. (8/9/13) 951:6-10.

¹⁹⁹ *Id.*

²⁰⁰ *Id.* at 951:11-16.

²⁰¹ Robinson Dep. (9/11/13) 1105:17-110:14.

²⁰² Robinson Dep. (9/11/13) 1114:15-18.

²⁰³ Robinson Dep. (9/11/13), 1115:5-19.

²⁰⁴ Chevron Materials Safety Data Sheet Marlex Polypropylenes (All Grades) Revision Number: 3 (Ex. T-3137).

contact with internal body fluids or tissues unless the material has been provided directly from Chevron Phillips Chemical Company LP under an agreement which expressly acknowledges the contemplated use.

Chevron Phillips Chemical Company LP makes no representation, promise, express warranty or implied warranty concerning the suitability of this material for use in implantation in the human body or in contact with the internal body fluids or tissues.

With respect to the Chevron Phillips MSDS, Ethicon Medical Director, Dr. Martin Weisberg, testified that he did not have the Chevron Phillips MSDS in 2001 when he reviewed the Sunoco MSDS and no one at Ethicon alerted him to it.²⁰⁵ If he had been alerted to the Chevron Phillips MSDS, it may have “triggered” an investigation on his part.²⁰⁶ He also believes that if Ethicon knew about this MSDS, Ethicon should have studied the issue and, if they did not do so, it would have been a violation of the company Credo.²⁰⁷

Total Petrochemicals, the polypropylene resin manufacturer for the polypropylene used in AMS’ pelvic floor products, Technical Data Sheet for Polypropylene PPR 7220, states in bold red lettering “Under no circumstances are any products sold by Total Petrochemicals suitable for human or animal implants.” It is further documented that, “The above-mentioned product is NOT in compliance with the US pharmacopoeia because we DID NOT perform required tests.” (emphasis from the original document).²⁰⁸

The manufacturer of the polypropylene resin for the polypropylene used in competitor pelvic floor products, Phillips Sumika Polypropylene Company, included a similar warning in its MSDS.²⁰⁹ Specifically, it states:

Do not use this Phillips Sumika Polypropylene Company material in medical applications involving permanent implantation in the human body or permanent

²⁰⁵ Weisberg Dep. (8/9/13) 944:16-945:5.

²⁰⁶ *Id.*

²⁰⁷ *Id.* at 947:4-19.

²⁰⁸ ETH.MESH.02026591.

²⁰⁹ Phillips Sumika Polypropylene Company Material Safety Data Sheet Marlex Polypropylene (All Grades) Revision Number: 5.03 Revision Date: 12/4/2008.

contact with internal body fluids or tissues. Do not use Phillips Sumika Polypropylene Company material in medical applications involving brief or temporary implantation in the human body or contact with internal body fluids or tissues unless the material has been provided directly from Phillips Sumika Polypropylene Company under an agreement which expressly acknowledges the contemplated use. Phillips Sumika Polypropylene Company makes no representation, promise, express warranty or implied warranty concerning the suitability of this material for the use in implantation in the human body or contact with internal body fluids or tissues.

As discussed above, the possibility that polypropylene mesh can cause tumors or cancer is documented in the Sunoco MSDS, the manufacturer of the polypropylene resin used in the TVT Prolene mesh.²¹⁰ Specifically, the Sunoco MSDS from April 13, 2005 states:

COMPONENT TOXICITY: Polypropylene has been tested in laboratory rats by subcutaneous implantation of discs or powder. Local sarcomas were induced at the implantation site. No epidemiological studies or case report suggest any chronic health hazard from long term exposure of polypropylene decomposition products below the irritation level.”²¹¹

Despite this warning in the MSDS for the polypropylene resin used to manufacture the TVT mesh, there is no evidence that Ethicon informed surgeon about this important information contained in various Manufacturer Safety Data Sheets (MSDS) regarding the use of polypropylene. This information includes the dangers of using polypropylene in a permanent implanted medical device set forth in MSDS that were in the public domain and available to Ethicon if they chose to look. Ethicon also failed to inform physicians that laboratory studies on rats showed that polypropylene caused sarcomas.

The fact that this information has not been disclosed to physicians in any manner (IFUs, direct letters or promotional materials) is especially concerning in light of literature showing reports of cancer associated with polypropylene. Specifically, there have been cases of

²¹⁰ ETH.MESH.02026591-6595.

²¹¹ ETH.MESH.02026595.

pseudotumor reported in polypropylene for hernia mesh²¹² and inflammatory myofibroblastic tumor of low malignant potential with a TVT device.²¹³ In addition, there have been 2 cases of bowel cancer associated with mesh used for abdominal sacrocolpopexy, one associated with mersilene and one with polypropylene and TVT placement.²¹⁴ A case of primary vaginal leiomyosarcoma associated with TVT and anterior repair with Bard Duraderm has also been reported.²¹⁵

Finally, a report of angiosarcoma associated with Darcon vascular grafts was reported in 1999.²¹⁶ The authors of this article noted at least 8 other sarcomas developing at the site of vascular prosthesis, and that the rate of these sarcoma, associated with foreign bodies, was much higher than the rate of sarcomas in general. All sarcomas associated with Dacron grafts were high grade histology and disseminated at the time of presentation. The authors also describe sarcoma reported at the site of other foreign bodies, such as shrapnel, bullets, steel plates and retained surgical sponges. They also note that the latency period from the acquisition of the foreign body and the development of sarcoma had a mean of 33 years. They document that a chronic foreign body reaction, the same "microscopic foreign body reaction" described by Dr. David Robinson in his Sept 2013 deposition as being clinically insignificant, was the etiology of this carcinogenesis. The authors also describe sarcomas developing in rodents after inert plastic polymers were placed in their soft tissue: "The sarcomas developed in rodents in which thick fibrous capsules developed around the implanted material." The authors conclude: "For unknown reasons, the cells in this inflammatory and repair process may undergo a malignant transformation, probably associated with oncogene activation and tumor suppressor gene

²¹² Karrem, M., Community Oncology, Volume 7/Number 4/April 2010.

²¹³ Kwon S., et al, Female Pelvic Med Reconstruct Surg, Volume 18, Number 4, July/August 2012.

²¹⁴ Ahuja, S., et al, Gynecol Surg 2011, 8:217-221.

²¹⁵ Moller, K., et al, Gynecologic Oncology 94 (2004) 840-842.

²¹⁶ Ben-Izhak, O., et al, Am J Surg Pathology, Issue: Volume 23 (11), 1999, p. 1418.

inactivation. Further studies are warranted to search for the mechanisms involved in foreign body tumorigenesis." To date no manufacturer of mesh products has investigated this oncogenic potential as the authors recommended. In a report from the International Agency for Research on Cancer: Surgical Implants and Other Foreign Bodies, "When several polymers were tested in rats according to the same experimental protocol, sarcoma incidences ranged from 70% (polypropylene) to 7% (silicone)."²¹⁷ "Polymeric implants prepared as thin smooth films (with the exception of poly(glycolic acid)) are POSSIBLY CARCINOGENIC TO HUMANS."²¹⁸

Given the fact that hernia mesh placement increased in the 1990's with the advent of laparoscopic placement, and that vaginal mesh placed for SUI and POP accelerated in the 2000's, we may be on the cusp of an ever increasing number of foreign body tumors associated with vaginal mesh. Ethicon did not undertake any long term testing to determine whether or not these warnings on the polypropylene resin manufacturers MSDS were associated with long term consequences for permanent human use. This is true despite the fact that Ethicon has knowledge of three of these cancer reports (Kwon, Moller and Ahuja) as they are referenced in Ethicon's 2013 Clinical Evaluation Report regarding TVT.²¹⁹

Additionally, there is no evidence that Ethicon made any effort to inform surgeons of important information contained in various Manufacturer Safety Data Sheets (MSDS) regarding the use of polypropylene. This information includes the dangers of using polypropylene in a permanent implanted medical device. And, that laboratory studies on rats showed that polypropylene caused sarcomas in laboratory rats. Clearly, these facts are critical information relevant to both the surgeon evaluating his or her treatment options and to the patient's informed

²¹⁷ International Agency for Research on Cancer, Summaries and Evaluations, Vol.:74 (1999).

²¹⁸ McGregor, D.B., et al, European Journal of Cancer 36 (2000) 307-313 (emphasis added).

²¹⁹ ETH.MESH.10150515.

consent decisions. As a result, Ethicon failed to act like a reasonable and prudent medical device manufacturer.

F. BENEFITS OF TVT-S OUTWEIGHED BY ITS COMPLICATIONS

It is my opinion, based on my training, experience and extensive review of the literature and Ethicon's internal documents that the benefits of the TVT-S are outweighed by the severe, debilitating and life changing complications associated with the medical device. It is clear that a substantial number of women who are implanted with the TVT-S have already and will continue to suffer chronic, debilitating erosions or pain, among other complications, and these life changing complications outweigh the benefits of the TVT-S, a device used to treat a quality of life issue.

This is especially true given that traditional surgeries like the Burch and pubovaginal slings are not associated with the frequency or extent of these life changing complications. The efficacy of the TVT-S is equivalent to the traditional surgeries like the Burch. Traditional surgeries are not associated with TVT-S mesh based complications like contraction and erosion, but rather with clinically significant erosion. And, further, although traditional surgeries can cause symptoms such as pain following surgery, including dyspareunia, the risk, duration, extent and severity of chronic pain including dyspareunia following the TVT-S is much greater than with traditional surgeries, and of course those surgeries do not result in the often untreatable complications and symptoms that result from the TVT-S mesh.

Unfortunately, although there have been a large number of studies and publications involving the TVT over the years, the quality of most of the studies is not good, and the amount of bias included in the studies and publications adds to the limited value that the studies offer about long term, severe and debilitating complications like chronic pain and erosions associated

with the TVT-S. The 2011 Cochrane Collaboration (Ogah) concluded that most trials involving mid-urethral slings had short follow-up and the quality of evidence was variable such that the quality of evidence for the majority of trials was moderate with a minority having low-to-moderate evidence.²²⁰ Few trials reported outcomes after 1 year and long term adverse effects had yet to be determined. There are only a handful of RCTs involving the TVT that are long term, and major and long term complications would unlikely be picked up in these RCTs in part because they are designed with a primary endpoint of efficacy, not safety. The true incidence are more likely to be determined by registries or databases, but published registries do not track certain complications such as pain or dyspareunia, and have not been designed to monitor long term problems (Tamussino, 2001 and 2007; Kuuva 2002, Collinet, 2008, Dykorn 2010). This void in studying and presenting the true incidence and nature of long term and life altering complications, along with the biases inherent in many of the studies, and other factors, negates the value of the large majority of the studies, and as a result, other sources of data such as published case series are relevant and important to truly understand the nature of these complications. Ethicon's internal documents and data, which are not publically available, present a very different picture of the TVT-S than the information that has been shared with patients and physicians.

G. ETHICON PROVIDED INADEQUATE TRAINING FOR IMPLANTING THE TVT-S

Though internal documents reflected Ethicon was aware of the multitude of problems associated with the implantation of the TVT-S, Ethicon failed to offer adequate training/retraining to physicians and did not revise the IFU. Ethicon made no effort to market the TVT-S to the most skilled physicians, despite feedback from their own KOLs. Alternatively,

²²⁰ Ohah, et. al., Minimally Invasive Synthetic Suburethral Sling Operations for Stress Urinary Incontinence in Women: A Short Version Cochrane Review. *Neurology and Urodynamics* 30:284-291 (2011).

Dan Smith, an engineer, was sent to train a number of surgeons around the world on how to correctly implant the TVT-S in addition to spearheading the direction of the product marketing. Internal Ethicon documents reflect knowledge of the inadequacy of its physician training as well as the deficiencies within the training programs.²²¹

On October 25, 2007, Dr. Aran Maree (Medical Director Australia/New Zealand) addressed the growing issue of failed TVT-S implants in Australia.²²² Based on information and different sources, Dr. Maree began inquiring into potential issues associated with the TVT-S in 2007. He noted the failure rates of three doctors in addition to Dr. Lucente's failure rates. Dr. Maree further stated he wasn't surprised at Dr. Lucente's rates as "[t]his is very different to the QA database numbers sent through from the 'reported' complaint rates by the USA sales earlier on."²²³ At the end of October 2007, Dr. Maree placed a "quality block" on the TVT-S in Australia and New Zealand, which prohibited the product from being released from the warehouse.²²⁴ On November 1, 2007, the decision was made to withdraw the TVT-S entirely from the Australian market.²²⁵ Subsequently, Dr. Maree emailed Catherine Beath stating: "We feel that withdrawing the product from the market here is currently the most appropriate action for Australia. We believe this to be appropriate until we are confident that a modified technique, appropriately documented and tested by way of clinical study, can be taught to our surgeons and will lead to optimal patient outcomes with this product."²²⁶ A dear doctor letter was mailed in

²²¹ETH.MESH.0324086; *see also* ETH.MESH.0329557; *see also* ETH.MESH.00330141; *see also* ETH.MESH.03922618; *see also* ETH.MESH.02105223; *see also* ETH.MESH.00874445 Page 17.

²²² ETH.MESH.00642325 Page 6.

²²³ ETH.MESH.03845446.

²²⁴ Dep. of Aran Maree 7.22.2013 at 189:14-190:22.

²²⁵ ETH.MESH.00326842.

²²⁶ ETH.MESH.00326842.

March 2008, explaining the concerns expressed by many surgeons.²²⁷ As a result of this letter, surgeons stopped using the product and shipped their remaining stock back to Ethicon.²²⁸

Thus, in Australia, the first concern about the TVT-S was raised in approximately September 2007—by early November 2007, the product was no longer being sold.²²⁹ No other countries were informed about the quality block or dear doctor letter in Australia.

Hi Aran

As discussed earlier today, below is a summary of the key reasons surgeons do not wish to be re-trained on TVT Secur a this point in time.

- lack of clinical evidence
- steep learning curve (ie Vince Lucentes data suggests the first 25 patients will have a high failure rate - surgeons aren't prepared to risk their patients)
- IFU versus "nuances" - very different
- Current data suggests success of 65-70% (Vince Lucente) which is significantly lower than the 85-90% proven success for TVT-O. Surgeons aren't willing to try new technology unless we are able to prove similar success rates via independent studies

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Ultimately, no Australian physicians elected to attend retraining on the TVT-S because they had no confidence in the device.²³¹

The TVT-S required specialized training and Ethicon was aware of this need. Dr. Maree testified that the TVT-S was a product that had either a “substantially” new technique or significant modification from the predicate devices.²³² Ethicon should have, but failed to, provide adequate, mandatory follow-up training. Dr. Ramy A. Mahmoud (WW VP for Evidence Based Medicine and CEO at Ethicon from 2007 to 2010) testified that he recalled discussing with Dr. Robinson and other surgeons the importance of proper technique in implanting the

²²⁷ ETH.MESH.05404976.

²²⁸ Dep. of Aran Maree 7.22.13 at 265:4-18.

²²⁹ Dep. of Aran Maree 7.22.13 at 271:14-22.

²³⁰ ETH.MESH.00823421-ETH.MESH.00823422.

²³¹ ETH.MESH.04127331.

²³² Deposition of Aran Maree 7.22.13 Page 137 Line 8-16

TVT-S and “how important the training was in order to adopt the correct technique in order to achieve the desired success rate.”²³³

In December 2006, Dr. Axel Arnaud (Medical Affairs Director of Ethicon, Europe Middle East and Africa) stated that even surgeons “who have been correctly trained and who have passed the learning phase, are raising concerns about the efficacy of the TVT Secur . . . They are asking for clear recommendations about the way to perform the procedure, in particular about the size of the dissection, the tension to be given to the tape and the way to perform a cough test,”²³⁴ none of which were disclosed in the TVT-S IFU.²³⁵ Dan Smith disagreed with Dr. Arnaud, finding Dr. Arnaud’s suggestions (the “cook book”) to be far too long with too much information in it. Dr. Arnaud emphasized that Ethicon could not “ignore that some surgeons who have been able in the past to successfully perform TVT and TVT-O are now struggling to achieve the same results with Secur.” Dr. Arnaud continued that he wished “the solution would just be to tell them to go back to their homework, but I am not sure it is the best one.”²³⁶ In the same internal communication, Dr. Robinson concluded that “it is just as clear that we are having some type of training problems and in order to prevent wide spread negative talk, I think we must take palliative steps quickly.”²³⁷

A March 14, 2007 email sent by Dr. Robinson to Dr. Axel Arnaud acknowledged that Ethicon’s first human use study taught “that the learning curve is longer than we thought, mesh tensioning is different than kits with sheaths and that following the IFU is important”²³⁸ During a June 18, 2008 interview, KOL Carl Nilsson stated that the learning curve for him with the TVT-

²³³ Deposition of Rahmy Mahmoud, MD 7.16.13 Page 380:5-10

²³⁴ ETH.MESH.00519479

²³⁵ ETH.MESH.02340568 (TVT-S IFU)

²³⁶ ETH.MESH.01784428, Page 2 and 3

²³⁷ ETH.MESH.01784428, Page 1

²³⁸ ETH.MESH.03922618

S was “100 patients before he was very good with very dry results.”²³⁹ Dr. Vincent Lucente, Ethicon Consultant and US KOL, had a 40% failure rate in first 25 patients, and 30% of his first 77 patients. Ethicon employees, including Dr. TC Khoo (VP of Strategic Medical Affairs for Asia Pacific) began to suspect that failed implantations were “related to operator based technique deployment.”²⁴⁰ Dr. Khoo sought to remedy any problems in training in order to “eliminate[ing] any possibility of product related issues while considering the adequacy of training and what is needed to properly rollout a device” so that patients do not get “the short end of the stick.”²⁴¹ Dr. Khoo found the “responsibility of controlling the adequacy of training is critical.”²⁴²

Around October 2007, Dr. Maree expressed his concerns that the “current training program may not result in competency in device insertion or result in clinical efficacy. There appear to be ‘tricks’ to insertion of the product and removal of the inserters which prevent dislodging the device in the process.”²⁴³ As Dr. Maree clearly stated to Ethicon, “the average practitioner finds it too complicated to insert correctly and cannot master the process.”²⁴⁴ Because of the difficulty of inserting the product and the inadequate training, which left surgeons unable to achieve competency in insertion, Dr. Maree recommended “restrict[ing] access to those who can.”²⁴⁵ An Ethicon memo regarding TVT-S by Mr. Smith noted the “implications” of achieving competency on the TVT-S: “extensive training requirements, possible loss of market share.”²⁴⁶ Despite complaints from its own KOLs, Ethicon “rushed” the TVT-S to market, marketed it to all surgeons (even though the most experienced surgeons were experiencing

²³⁹ ETH.MESH.04048515 at 3.

²⁴⁰ ETH.MESH.00642325 Page 3

²⁴¹ *Id.*

²⁴² *Id.*

²⁴³ ETH.MESH.00642330- ETH.MESH.00642331.

²⁴⁴ ETH.MESH.00642327.

²⁴⁵ *Id.*

²⁴⁶ ETH.MESH.00858636-639 (“Do not underestimate the learning curve for a device which seems simple”).

difficulties obtaining successful results with the device), and failed to ever restrict access to this device.

V. CONCLUSION

Ethicon marketed and sold the TVT-S despite the fact that it had numerous characteristics making it unsuitable and not reasonably safe for implantation in a woman's vagina. Among other noted herein, these characteristics include the following: (1) excessive rigidity; (2) degradation of the mesh; (3) chronic foreign body reaction; (4) infections and bio-films; (5) fibrotic bridging leading to scar plate formation and mesh encapsulation; and (6) shrinkage/contraction of the encapsulated mesh.

Regardless of skill level, there were numerous known risks by Ethicon that were undisclosed in the TVT-S' IFU. Not only did Ethicon sell a product which should never be put in the vagina, it failed to inform physicians and their patients about numerous risks associated with the product despite the fact that these risks were known before the product was launched. The IFU warnings that were provided were wholly inadequate and, coupled with the device's various defects, demonstrate the TVT-S was unreasonably dangerous as sold. Ethicon has removed the ability of physicians to appropriately inform their patients of the risks and benefits of the TVT-S and made it impossible for women to consent to the procedure. In addition, despite having knowledge to the contrary, Ethicon never informed physicians and their patients that the TVT-S was associated with cancer and could be toxic to their bodies. Finally, while keeping this information from women, Ethicon marketed its product with promotional pieces that did not disclose key conflict of interest information or the true complication rates of its products.

As a result of these failures, the TVT-S has caused and will continue to cause a multitude of injuries in women, including the potential for multiple erosions that can occur throughout one's lifetime, chronic and debilitating pelvic pain, nerve injury, recurrence, worsening incontinence, chronic dyspareunia, wound infection, rejection of the mesh, sexual dysfunction, urinary and defecatory dysfunction, vaginal scarring, wound healing problems, injury to ureters, pelvic abscess formation, risk of infection, and/or the need for additional surgeries, among others.

All opinions I have are to a reasonable degree of medical certainty. I reserve my right to amend my opinions if further information is provided in any form including, but not limited to, corporate documents, depositions and expert reports of both Plaintiff and Defense experts.

Date of Report: January 22, 2016.

Sincerely,

A handwritten signature in black ink, appearing to read 'BR', with a long horizontal flourish extending to the right.

Bruce Rosenzweig, M.D.

EXHIBIT A

Bruce A. Rosenzweig, MD

CURRICULUM VITAE

NAME: **Bruce A. Rosenzweig, M.D.**

ADDRESS: 175 East Delaware Suite 8909
Chicago, Illinois 60611

DATE OF BIRTH: November 16, 1957

PLACE OF BIRTH: New York City, New York

MARITAL STATUS: Married

EDUCATION: **Fellowship**

1989 - 1991 Urologic Gynecology and Urodynamics
Harbor/UCLA Medical Center
Department of Obstetrics and Gynecology
Torrance, California

1988 - 1989 Pelvic Surgery
State University of New York
Department of Obstetrics and Gynecology
Syracuse, New York

Residency

1984 - 1988 Obstetrics and Gynecology
Michael Reese Hospital and Medical Center
Department of Obstetrics and Gynecology
Chicago, Illinois

1987 - 1988 Administrative Chief Resident

Graduate

1980 - 1984 University of Michigan Medical School
Ann Arbor, Michigan

1980 - 1984 Academic Tuition Scholarship
University of Michigan Medical School

Undergraduate

1976 - 1980 University of Michigan
Ann Arbor, Michigan - BS in Zoology
1976 University of Michigan Alumni Scholarship,
Illinois Chapter
1976 Bronsted Freshman Prize

Bruce A. Rosenzweig, MD

POSITIONS/APPOINTMENTS:

2011- 2012	Associate Chair Weiss Memorial Hospital Department of Gynecology Chicago, Illinois
2003- 2010	Attending Physician John H. Stroger Jr. Hospital Department of Obstetrics and Gynecology Chicago, Illinois
2002 - Present	Attending Physician Department of Obstetrics and Gynecology Rush Presbyterian St. Luke Hospital Chicago, Illinois
2002 - Present	Assistant Professor Rush Medical College Chicago, Illinois
1997 - 2005	Attending Physician Department Obstetrics and Gynecology Mercy Hospital and Medical Center Head Urogynecology Chicago, Illinois
1995 - 1998	Attending Physician Department of Women's Health Department of Veterans Affairs Westside Veterans Hospital Chicago, Illinois
1994 - 1998	Associate Professor Department of Obstetrics and Gynecology and Department of Urology University of Illinois, College of Medicine Chicago, Illinois
1992 - 1994	Assistant Professor Department of Urology University of Illinois, College of Medicine Chicago, Illinois
1991 - 1998	Associate Residency Program Director Department of Obstetrics and Gynecology University of Illinois, College of Medicine Chicago, Illinois
1991 - 1998	Head of Gynecologic Urology Department of Obstetrics and Gynecology University of Illinois, College of Medicine Chicago, Illinois
1991 - 1998	Attending Physician Department of Obstetrics and Gynecology Michael Reese Hospital and Medical Center Chicago, Illinois

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POSITIONS/APPOINTMENTS (Cont):

1991 - 1994	Assistant Professor Department of Obstetrics and Gynecology University of Illinois, College of Medicine Chicago, Illinois
1990 - 1991	Clinical Instructor Department of Obstetrics and Gynecology UCLA School of Medicine Los Angeles, California
1989 - 1991	Attending Physician Department of Obstetrics and Gynecology Harbor/UCLA Medical Center Torrance, California
1988 - 1989	Clinical Instructor Department of Obstetrics and Gynecology State University of New York Health Science Center Syracuse, New York
1988 - 1989	Attending Physician Department of Obstetrics and Gynecology Crouse-Irving Memorial Hospital Syracuse, New York

PROFESSIONAL SPORTS TEAM PHYSICIAN

2011- Present	Chicago Sky Women's Basketball Team
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LICENSURE:

1984	State of Illinois, #036-071719
1988	State of New York, #175147 (inactive)
1989	State of California, #G065470 (inactive)
1985	State of Illinois Controlled Substance, #003-136655
1985	DEA #BR0291815

SPECIALTY BOARDS:

1985	Diplomate of National Board of Medical Examiner
1991	Diplomate of American Board of Obstetrics and Gynecology (Recertified 2005)

JOURNAL EDITORIAL BOARD:

JOURNAL OF GYNECOLOGIC SURGERY
JOURNAL REVIEWER AND CONSULTANT

OBSTETRICS AND GYNECOLOGY

JOURNAL OF GYNECOLOGIC SURGERY

SURGERY GYNECOLOGY AND OBSTETRICS
ABSTRACTOR: International Abstracts of Surgery;

INTERNATIONAL UROGYNECOLOGY JOURNAL

Bruce A. Rosenzweig, MD

JOURNAL EDITORIAL BOARD (Cont):

JOURNAL OF THE AMERICAN MEDICAL ASSOCIATION
CONSULTANT: Diagnostic and Therapeutic Technology
Assessment (DATTA),

AMERICAN JOURNAL OF OBSTETRICS AND GYNECOLOGY

PSYCHOSOMATIC MEDICINE

SOUTHERN MEDICAL JOURNAL

JOURNAL OF HOSPITAL MEDICINE

INTERNATIONAL JOURNAL OF OBSTETRICS AND GYNECOLOGY

TEACHING AWARDS:

1997	CREOG National Faculty Resident Teaching Award
1993	APGO Excellence in Undergraduate Medical Education Award

MEDICAL ADVISORY BOARDS:

1993 - 1995	EMPI, Inc. St. Paul, Minnesota
1997 - 1999	EmpowerMed Yardley, Pennsylvania
2001 - 2003	Medcases Philadelphia, Pennsylvania

MEMBERSHIP ACTIVITIES AND COMMITTEES:**Michael Reese Hospital and Medical Center**

1987 - 1988	Chief Resident's Council
1987 - 1988	Residency Evaluation Committee
1988	Hospital Utilization Review Committee

Harbor-UCLA Medical Center

1989 - 1991	Surgical Case Review Committee.
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University of Illinois at Chicago, College of Medicine

1991 - 1993	Committee on Hospital Infections
1991 - 1997	OB/GYN Department Quality Assurance Committee
1991 - 1993	Medical Staff Quality Assurance Committee
1993	Ad Hoc Pap Smear Task Force
1993	Ad Hoc Committee to Review the 5 Year Deceleration Medical Student Program
1995 - 1997	Medical Records Committee
1996 - 1997	Generalist Curriculum Subcommittee
1997	Committee to Review the Performance of the Head of the Department of Urology

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GRANTS AND CONTRACTS:

1989 - 1990	#PQ 1402-02B Investigator "A Randomized, Controlled, Comparative Clinical Trial of Thiamphenicol Glycinate/Thiamphenicol Versus Cefoxitin/Doxycycline in the Treatment of Pelvic Inflammatory Disease." Sponsor: <i>Pharmaquest Corporation</i>
1989 - 1991	#35614-87 Investigator "A Randomized, Open-Label, Comparative, Multicenter, Safety, Tolerance and Efficacy Study of Parenteral Piperacillin/Tazobactam (CL 298.741) versus Clindamycin Plus Gentamicin in the Treatment of Hospitalized Patients with Gynecologic Infections." Sponsor: <i>American Cyanamid</i>
1990 - 1991	#MDS 401-US Investigator "Micturin versus Placebo in the Treatment of Urge Incontinence in Females. " Sponsor: <i>Forest Laboratories</i>
1992 - 1993	#C91-002 Principal Investigator "A Six Month Evaluation of Efficacy, Safety and Tolerance of the Lea's Shield. A Vaginal Barrier Contraceptive Device." Sponsor: <i>Contraceptive Research and Development Program</i>
1995 - 1997	#1393-027 Principal Investigator "Phase II Safety and Efficacy Study of Fem Cap Used With and Without Spermicide. " Sponsor: <i>Contraceptive Research and Development Program</i>

INVENTIONS AND PATENTS:

1. Double Lumen Amnioinfusion Catheter. U.S. Patent Number 4,722,730,
February 2, 1998. "Amcath". Manufactured by Gish Biomedical, Santa Ana, California.
2. "Meconium Aspirator Set." Manufactured by Gish Biomedical, Santa Ana, California.

VIDEO PRESENTATIONS:

Freedman A, Rosenzweig B, Maurice J., An Interesting Presentation of Failed Medical Termination with Hysteroscopic Resection of Retained Products of Conception. 41st Global Congress of minimally Invasive Gynecology Las Vegas, Nevada November 2012

MULTIMEDIA

FILM

1. *Design*. Feature Film. Premiere Sundance Film Festival January 2002. Co-Producer.
2. *Kwik-Stop*. Feature Film. Premiere Los Angeles Film Festival April 2001. Actor.
3. *The 95th*. Documentary. Premiere Maryland Film Festival May 2002. Co-Producer.
4. *Independent films and filmmakers*. Short Documentary. 1998. Producer, Director.

COMPUTER INTERACTIVE TEACHING PROGRAMS

Urogynecology: Evaluation and Treatment of Urinary Incontinence. CD Rom; Produced
by Interactive Medical Review, Philadelphia, Pennsylvania, 1994.

MULTIMEDIA (Cont):

Bruce A. Rosenzweig, MD

STREAMING MEDIA

1. Live Webcast of the First Streaming Media Conference. 1998. Producer, Director.

INDUSTRIAL VIDEO

1. *A Day at the Office*. WellSpring Management Group, Bethany, Connecticut. 1998. Producer, Director.
2. *Point of View Skiing*. American Ski Corporation, Sugarbush, Vermont. 1998. Producer.
3. *Promotional Video*. IMET Coporation, Philadelphia, Pennsylvania. 1999. Producer, Director.

PRESENTATIONS AND INVITED LECTURES:

Michael Reese Hospital and Medical Center

1. "A Prospective Randomized Study Comparing Nipple Stimulation and Exogenous Oxytocin Contraction Stress Tests." Presented at the First Annual Resident Research Conference, Michael Reese Hospital and Medical Center, Chicago, Illinois. June 11, 1987.
2. "Postpartum Uterine Inversion." Grand Rounds, Michael Reese Hospital and Medical Center, Chicago, Illinois. September 10, 1987.
3. Faculty Member: Basic and Advanced Laser Surgery, Hysteroscopy, Colposcopy, and Operative Laparoscopy, A "Hands-On" Course and Seminar, Washington, DC. January 25-28, 1989.
4. "Tubo-ovarian Abscess: Medical versus Surgical- Management." Grand Rounds, University of Nairobi, Nairobi, Kenya. March 2, 1989.
5. "HPV DNA and Squamous Atypia." Presented at the Tenth Annual Scientific Congress and Advanced Postgraduate Laser Course of the Gynecologic Laser Society, Orlando, Florida. March 31, 1989.
6. "Postpartum Uterine Inversion: Diagnosis and Management." Grand Rounds, SUNY-HSC, Syracuse, New York. March 17, 1989
7. Faculty Member: Basic and Advanced Laser Surgery: A Complete 5-Day "Hands-On" Course and Seminar, Virginia Beach, Virginia. July 24-28, 1989.
8. "HPV: The Disease of the 80's." Presented at the Los Angeles Regional Family Planning Council Family Planning Symposium, Torrance, California. January 20, 1990.
9. Faculty Member: Basic and Advanced Laser Surgery, Diagnostic and Operative Hysteroscopy, Advanced Colposcopy, Laser Laparoscopy, and Pelviscopy, A "Hands-On" Course and Seminar, Washington, DC. January 24-27, 1990.
10. "Office of Evaluation of Urinary Incontinence." Luncheon Conference at the Thirty-Eighth Annual Meeting of the American College of Obstetricians and Gynecologists, San Francisco, California. May 8, 1990.
11. Faculty Member: Basic and Advanced Laser Surgery, Diagnostic and Operative Hysteroscopy, Advanced Colposcopy, Laser Laparoscopy, Pelviscopy. A complete 5-Day "Hands-On" Course and Seminar, Palm Beach, Florida. July 23-27, 1990.
12. "Lasers in Gynecology." Grand Rounds, Martin Luther King, Jr./Drew Medical Center, Los Ancreles, California. September 27, 1990.
13. "Urinary Incontinence and Genital Prolapse." Grand Rounds, HarborUCLA Medical Center, Torrance, California. October 15, 1990.

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PRESENTATIONS AND INVITED LECTURES (Cont):

14. Course Director: Contraceptive Technology: Symposium on Managing the IUD Patient. Planned Parenthood of San Diego and Riverside Counties, San Diego, California. October 27, 1990.

15. "Lasers in Urogynecology." Grand Rounds, Martin Luther King, Jr./Drew Medical Center, Los Angeles, California. November 8, 1990.

16. Course Director: Contraception in the 90's, Managing the IUD Patient. Oklahoma State Department of Health Maternal and Child Health Services, Oklahoma City, Oklahoma. March 1, 1991.

17. "Office Evaluation of Urinary Incontinence." Grand Rounds, Michael Reese Hospital and Medical Center, Chicago, Illinois. April 4, 1991.

18. Urinary Incontinence and Genital Prolapse. " Grand Rounds, University of Illinois at Chicago, College of Medicine, Chicago, Illinois. April 8, 1991.

19. "Urinary Incontinence." Women's Healthcare Center, Torrance, California. April 25, 1991.

20. "Evaluation and Management of Urinary Incontinence." South Bay Perinatal Access Project, San Pedro, California. May 3, 1991.

21. "Office Evaluation of Incontinent Women." Luncheon Conference at the Thirty-Ninth Annual Meeting of the American College of Obstetricians and Gynecologists, New Orleans, Louisiana. May 7, 1991.

22. "Surgical Choices for Incontinence. " Luncheon Conference at the Thirty-Ninth Annual Meeting of American College of Obstetricians and Gynecologists, New Orleans, Louisiana. May 8, 1991.

23. AUGS Special Interest Session: "Gynecological Urology: Case Management in Urogynecology. At the Thirty-Ninth Annual Meeting of the American College of Obstetricians and Gynecologists, New Orleans, Louisiana. May 8, 1991.

24. "Vulvar and Vaginal Diseases." Colposcopy Training Course, Torrance, California. May 30, 1991.

25. "Managing the IUD Patient." Grand Rounds, Glendale Adventist Hospital, Glendale, California. June 10, 1991.

26. Course Director: Managing the IUD Patient. Arizona Family Planning Council, Phoenix, Arizona. June 15, 1991.

27. "Basic Urogynecologic Instrumentation; Proper Evaluation and Differential Diagnosis of Stress Urinary Incontinence." Gynecologic and Endoscopic Surgery. A Complete 5-Day "Hands-On" Course and Seminar, Palm Beach, Florida. July 22, 1991.

28. "Evaluation and Management of Urinary Incontinence." At the Fourth Annual National Association of Womens' Health Professional Conference, Chicago, Illinois. October 17, 1991.

29. Course Coordinator: Advanced Diagnostic and Therapeutic Techniques in Obstetrics and Gynecology: A Hands-On Seminar. "Evaluation of the Incontinent Patient; IUD Update; Nonsurgical Management of the Incontinence." Advanced Diagnostic and Therapeutic Techniques in Obstetrics and Gynecology, Snowbird, Utah. March 11-14, 1992.

30. "Managing the IUD Patient." Grand Rounds, Jackson Park Hospital, Chicago, Illinois. March 19, 1992.

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PRESENTATIONS AND INVITED LECTURES (Cont):

31. "Evaluation and Nonsurgical Management of the Incontinent Patient." Grand Rounds, Jackson Park Hospital, Chicago, Illinois. April 2 & 19, 1992.
32. "Nonsurgical Management of Urinary Incontinence." Grand Rounds, and "Evaluation of the Incontinence Patient." Visiting Professor Lecture, Albert Einstein Hospital, Philadelphia, Pennsylvania. April 6, 1992.
33. "Nonsurgical Management of Urinary Incontinence." Grand Rounds, Michael Reese Hospital, Chicago, Illinois. April 7, 1992.
34. "Surgery in the Elderly. Female Urinary Incontinence: A Gynecologists Point of View." At the United States Section of the International College of Surgeons, Chicago, Illinois. April 10, 1992.
35. "Managing the IUD Patient." American College of -Nurse Midwives. Illinois Chapter Meeting. University of Illinois, College of Nursing, Chicago, Illinois. April 13, 1992.
36. "Contraceptive Choices in the 1990's." Postgraduate Course at the Annual Clinical Meeting of the American College of Obstetricians and Gynecologists, Las Vegas, Nevada. April 28-29, 1992.
37. "IUD and Contraception." Grand Rounds, Mount Sinai Hospital and Medical Center, Chicago, Illinois. May 6, 1992.
38. "Genital Prolapse and Lower Urinary Tract Dysfunction." Grand Rounds, Cook County Hospital, Chicago, Illinois. May 11, 1992.
39. "Managing the IUD Patient." Grand Rounds, Ravenswood Hospital, Chicago, Illinois. May 21, 1992.
40. "Nonsurgical Management of Urinary Incontinence. Grand Rounds, Humana Hospital/Michael Reese and Medical Center, Chicago, Illinois. June 4, 1992.
41. "Urinary Dysfunction." Obstetrics and Gynecology Review Course, Chicago, Illinois. June 5, 1992.
42. "Surgical Management Stress Incontinence of Urine; Management of Operative Complications; Comparison of Techniques for Management of CIN. Advanced Gynecologic Surgery: A Complete 5-Day "Hands-On" Course and Seminar, Palm Beach, Florida. July 20-22, 1992.
43. "Nonsurgical Management of Urinary Incontinence." Grand Rounds, Cook County Hospital, Chicago, Illinois. July 27, 1992.
44. "Nonsurgical Approach to Female Incontinence." Grand Rounds, Alexian Brothers Medical Center, Elk Grove Village, Illinois. September 3, 1992.
45. Course Director: Update on Urogynecology. "Evaluation of the Incontinent Patient; Nonsurgical Management of Stress Urinary Incontinence." Update on Urogynecology, Philadelphia, Pennsylvania. September 21, 1992.
46. "Urinary Incontinence: It Doesn't Have to be Part of a Woman's Everyday Life." Virginia Baptist Hospital, Lynchburg, Virginia. October 13, 1992.
47. "Managing the IUD Patient. Grand Rounds, Hershey Medical Center, Hershey, Pennsylvania. October 21, 1992.
48. "Nonsurgical Management of Urinary Incontinence." Grand Rounds, University of Illinois at Champaign, Champaign, Illinois. October 28, 1992.

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PRESENTATIONS AND INVITED LECTURES (Cont):

49. "Evaluation and Management of Urologic Problems in Women. " Gynecological Update 1991, La Mesa, California. October 31, 1992.

50. "IUD Insertion/Removal and Model Practicum. At the Annual Family Planning, Obstetrics and Gynecology Update for Florida Nurse Practitioners, Orlando, Florida. November 5, 1992.

51. "IUD's Revisited." At the Statewide Clinician's Meeting, Planned Parenthood Wisconsin, Milwaukee, Wisconsin. November 13, 1992.

52. "The Nonsurgical Management of Stress Urinary Incontinence." Grand Rounds, University Hospital of Cleveland, Cleveland, Ohio. November 18, 1992.

53. "The IUD: A Second Look." A Contraceptive Symposium and Practicum. San Bernadino County Department of Public Health. Womens' Health Section, San Bernadino, California. November 20, 1992.

54. "Managing the IUD Patient." Grand Rounds, Department of Family Practice, University of Illinois, Chicago, Illinois. December 2, 1992.

55. "Managing the IUD Patient." Grand Rounds, West Pennsylvania Hospital, Pittsburgh, Pennsylvania. January 12, 1993.

56. "Repair of Pelvic Floor Dysfunction; Voiding Disorders and How to Manage Them." Advanced Gynecologic Surgery, Washington, D.C. January 27, 1993.

57. Course Director: Controversies in Gynecology. "Nonsurgical Management of Stress Urinary Incontinence; Genital Prolapse and Lower Urinary Tract Dysfunction Controversies in Gynecology, St. Petersburg, Florida. February 11-12, 1993.

58. "Genital Prolapse and Lower Urinary Tract Dysfunction." Grand Rounds, Saginaw General Hospital, Saginaw, Michigan. February 15, 1993.

59. "Managing the IUD Patient." Oklahoma State Department of Health Practitioners Annual Meeting, Oklahoma City, Oklahoma. March 11, 1993.

60. Course Director: Advanced Diagnostic and Therapeutic Techniques in Obstetrics and Gynecology. "Genital Prolapse and Lower Urinary Tract Dysfunction; Physiotherapy in the Treatment of Lower Urinary Tract Dysfunction; Surgical Management of Stress Urinary Incontinence; The Role of IUD's in Contraception." Beaver Creek Colorado. March 17-20, 1993.

61. "Managing the IUD Patient." Grand Rounds, Waukesha Memorial Hospital, Waukesha, Wisconsin. March 23, 1993.

62. "Genital Prolapse and Lower Urinary Tract Dysfunction." Grand Rounds, Evanston Hospital, Evanston, Illinois. March 25, 1993.

63. "Evaluation of the Incontinent Patient." Grand Rounds, West Pennsylvania Hospital, Pittsburgh, Pennsylvania. March 29, 1993.

64. "Managing the IUD Patient." Grand Rounds, Forbes Metro Hospital, Pittsburgh, Pennsylvania. March 30, 1993.

65. "Incontinence Differential Diagnosis, History and Physical Exam; Pelvic Floor Neurology for the Gynecologist: EMG and Pudendal Conduction Latency; Other Cause of Incontinence." At Urogynecology 1993 State of the Art, Frisco, Colorado. April 2-3, 1992.

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PRESENTATIONS AND INVITED LECTURES (Cont):

66. "Intrauterine Device: Insertion and Management." Sixteenth Annual Seminar in Womens' Health Care, Dallas, Texas. April 16, 1993.

67. "Contraceptive Choices for the 1990's and Beyond." The Annual Clinical Meeting of the American College of Obstetricians and Gynecologists, Washington, D.C. May 4-5, 1993.

68. "Managing the IUD Patient." Grand Rounds, La Grange Hospital, La Grange, Illinois. May 17, 1993.

69. "Evaluation and Management of Urinary Incontinence." Grand Rounds, Mount Sinai Hospital, Miami, Florida. May 25, 1993.

70. "Contraceptive Update." At the Tenth Annual Medical Update, Pittsburgh, Pennsylvania. June 2, 1993.

71. "Treatment of Urinary Incontinence." Obstetrics and Gynecology Review Course, Chicago, Illinois. June 10, 1993.

72. "Open Urinary Stress Incontinence Procedures." St. Louis, Missouri. June 16, 1993.

73. "Nonsurgical Management of Urinary Incontinence." Grand Rounds, Baylor College of Medicine, Houston, Texas. June 30, 1993.

74. "Urodynamic Testing; Nonsurgical Management of Urinary Incontinence; Bladder Injury: How to Avoid, How to Manage." At Principles of Advanced Conventional and Endoscopic Surgery, Palm Beach, Florida. July 26, 1993.

75. "Evaluation, Diagnosis and Management of Urinary Stress Incontinence." The Gynecologic Surgical Techniques, Chicago, Illinois. August 19, 1993.

76. "Pelvic Anatomy and Placement of Sutures for Paravaginal Repair and Correction of Stress Incontinence." Demonstrated Using Human Cadaver, Chicago, Illinois. August 20, 1993.

77. Course Director: Practical Urogynecology. "Behavioral Management of Incontinence; Painful Voiding Syndrome; Behavioral and Physical Therapy for Urinary Incontinence." Cleveland, Ohio. August 27-38, 1993.

78. "Evaluation of the Incontinent Patient." Resident Lecture, East Carolina University, Greenville, North Carolina. September 22, 1993.

79. "Non-Hormonal Contraception." Grand Rounds, East Carolina University, Greenville, North Carolina, September 22, 1993.

80. "Gynecologic Disorders; Pregnancy Changes and General Surgical Problems During Pregnancy." Specialty Review in Surgical Critical Care, Chicago, Illinois, October 4, 1993.

81. "Managing the IUD Patient." Grand Rounds, George Baptist Medical Center, Atlanta, Georgia, October 12, 1993.

82. "Managing the IUD Patient." Grand Rounds, Reading, Pennsylvania. October 19, 1993.

83. "IUD Update: Clinical and Demographics Issues." Grand Rounds, Ohio State University, Columbus, Ohio. November 4, 1993.

84. "Update on Amnioinfusion." Grand Rounds, St. Francis Hospital, Blue Island, Illinois. November 16, 1993.

85. "Management of Urinary Stress Incontinence." St. Michael's Hospital, Toronto, Ontario, Canada. December 6, 1993.

86. "IUD Update: Clinical and Demographic Issues." Grand Rounds, Jackson Memorial

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Hospital, Miami, Florida. January 12, 1994.

PRESENTATIONS AND INVITED LECTURES (Cont):

87. "Urogynecology: Differential Diagnosis and Evaluation of Female Incontinence; Surgical Therapies for Stress Incontinence; Diagnosis and Treatment of Detrusor Instability; Diagnosis and Surgical Therapies for Stress Incontinence, Gynecologist." At Frontiers in Gynecology,

Steamboat Springs, Colorado. January 25-26, 1994.

88. "Genital Prolapse and Lower Urinary Tract Dysfunction." At the Fifth Annual Midwest Clinical Conference, Chicago Medical Society, Chicago, Illinois. February 11, 1994.

89. "Bacterial Vaginosis." Grand Rounds, Chicago Osteopathic Hospital, Chicago, Illinois. February 17, 1994.

90. "Gynecologic Problems in Surgery." At the Specialty Review in General Surgery, Chicago, Illinois. February 18, 1994.

91. "Female Urinary Incontinence: Anatomy Physiology, Definitions; Diagnosis and Management of Detrusor Instability; Painful Bladder Syndromes: Interstitial Cystitis, Urethral Syndrome, etc.; Diagnosis and Treatment of Pelvic Floor Disorders; Cystourethroscopy: Instrumentation and Technique; Ureteral Catheterization - Indications, Risks, Benefits." At Modern Menopause and Urogynecology, San Francisco, California. March 11-13, 1994.

92. "Nonsurgical Management of Urinary Incontinence." Grand Rounds, Kaiser Bellflower, Bellflower, California. March 29, 1994.

93. "Female Urinary Incontinence: Anatomy, Physiology, Definitions; Office Evaluation and Advanced Urodynamic Testing; Diagnosis and Management of Detrusor Instability; Painful Bladder Syndromes: Interstitial Cystitis, Urethral Syndrome, etc., Nonsurgical Therapies for Stress Incontinence; Cystourethroscopy: Instrumentation and Technique; Ureter Catheterization Indications, Risks, Benefits." At the Advanced Gynecologic Endoscopy with Urogynecology, Palm Springs, California. April 9-10, 1994.

94. "Intrauterine Device: Insertion and Management" at the 17th Annual Seminar in Womens' Health Care. Dallas, Texas. April 15, 1994.

95. "Surgical Management of Stress Urinary Incontinence." Grand Rounds, University of Illinois, Champaign, Illinois. April 15, 1994.

96. "Anatomy of Pelvic Floor Supporting System; Rational Anatomical Approach to Pelvic Floor Defects." At Advanced Laparoscopic Techniques, Chicago, Illinois. April 21, 1994.

97. "Managing the IUD Patient." Grand Rounds, University of Wisconsin, Milwaukee, Wisconsin. April 27, 1994.

98. "Contraceptive Choices." At the Annual Clinical Meeting of the American College of Obstetricians and Gynecologists. Orlando, Florida. May 10-11, 1994.

99. "Update on the IUD: New Friend or Old Danger." Grand Rounds, Harbor-UCLA Medical Center, Torrance, California. May 23, 1994.

100. "Contraception." At the Specialty Review in Obstetrics and Gynecology, Chicago, Illinois. May 24, 1994.

101. "Problem Management: IUD's. At the Twenty-Second Annual Conference for Nurse Practitioners in Reproductive Healthcare. Milwaukee, Wisconsin. June 10, 1994.

102. "Pelvic Floor Disorder." At the Obstetrics and Gynecology Review Course, Chicago, Illinois. June 15, 1994.

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PRESENTATIONS AND INVITED LECTURES (Cont):

103. "Female Urinary Incontinence: Treatment by Electrostimulation." Grand Rounds, Hospital du Sacre-Coeur, Montreal, Canada. June 16, 1994.

104. "Nonsurgical Management of Urinary Incontinence." Grand Rounds, Sparrow Hospital, Lansing, Michigan. June 21, 1994.

105. "Major Pelvic Hemorrhage: The Safest and Best Methods for Control; Vaginal Cones and Electrical Stimulation to Manage Stress Incontinence; What To Do With The Patient Who Continues To Leak After Multiple Incontinence Surgeries." At Operative Gynecology, Palm Beach, Florida. July 18-20, 1994.

106. "Repair of Genital Prolapse." Grand Rounds, Michael Reese Hospital, Chicago, Illinois. August 17, 1994.

107. "Evaluation, Diagnosis and Management of Urinary Stress Incontinence, Including Cystoscopy; Pelvic Anatomy and Placement of Sutures for Paravaginal Repair, Sacrospinous Fixation, and Connection of Stress Incontinence." At Gynecologic Surgical Techniques, Chicago, Illinois. August 18-19, 1994.

108. "Gynecologic Problems in Surgery; Surgery in Pregnant Women." At Specialty Review in General Surgery, Part I, Chicago, Illinois. August 22, 1994.

109. "Managing the IUD Patient." Grand Rounds, Medical College of Wisconsin, Milwaukee, Wisconsin. August 25, 1994.

110. "Managing the IUD Patient." Grand Rounds, Rush University, Chicago, Illinois. September 8, 1994.

111. "Gynecologic Problems in Surgery." At Specialty Review in General Surgery, Chicago, Illinois. September 19, 1994

112. "IUD Symposium." At the Colorado Department of Public Health, Womens' Health Symposium, Silverthorne, Colorado. October 5, 1994.

113. "Urinary Incontinence." Grand Rounds, St. Elizabeth Hospital, Chicago, Illinois. October 18, 1994.

114. "Nonsurgical Management of Urinary Incontinence." Grand Rounds, Christ Hospital, Oak Lawn, Illinois. October 24, 1994.

115. "Evaluation of Urinary Incontinence and the Bladder Neck Suspension." Atlanta, Georgia. November 18, 1994.

116. "Managing the IUD Patient." Grand Rounds, Mount Sinai Hospital, Hartford, Connecticut. January 6, 1995.

117. "Managing the IUD Patient." At the New Mexico Department of Health Clinicians Seminar, Albuquerque, New Mexico. January 26, 1995.

118. "Gynecologic Problems in Surgery." At the Specialty Review in General Surgery, Chicago, Illinois. February 2, 1995.

119. "Urinary Incontinence in Women." At the Womens' Health Issues 1995, India Medical Association (IL), USA, Chicago, Illinois. March 12, 1995.

120. "Bacterial Vaginosis." Grand Rounds, Anchor HMO, Chicago, Illinois. March 28, 1995.

121. "Urinary Incontinence in Women: What's New." Metropolitan Chapter of the American

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College of Surgeons Meeting, Chicago, Illinois. April 27, 1995.

PRESENTATIONS AND INVITED LECTURES (Cont):

122. "Evaluation of the Incontinent Patient; Surgical Management of SUI - Open Approach." at the Operative Laparoscopy, Hysterectomy, Pelvic Floor Repair and Hysteroscopy for Gynecologist. Atlanta, Georgia, June 16-17, 1995.

123. "Diagnosis and Management of Detrusor Instability; Painful Bladder Syndromes: Interstitial Cystitis, Urethral syndrome, etc; Cystourethros copy - instrumentation and techniques; Urethral Catheterization indications, risk, benefits; abdominal procedures for GSI; non surgical therapy for GSI." at Advanced Gynecology Endoscopy and Uro-gynecology, Vancouver, Canada, August 19, 1995.

124. "Evaluation of the Incontinent Patient; Surgical Management of SUI - Open Approach." At the Operative Laparoscopy, Hysterectomy, Pelvic Floor Repair and Hysteroscopy for Gynecologist. Atlanta, Georgia, September 29-30, 1995.

125. "Managing the IUD Patient." At The Regional meeting of AMWA. Chicago, Illinois, September 23, 1995.

126. "The Evaluation of the Incontinent Patient and Bladder Neck Suspension." At the Operative Laparoscopy, Hysterectomy, Hysteroscopy and Pelvic Floor Repairs for gynecologists. Atlanta, Georgia, September 29-30, 1995.

127. "Manaaement of Severe Genital Prolapse. " Grand Rounds - University of Illinois Champaign, Illinois November 1, 1995.

128. "Pelvic Prolapse. " at the Obstetrics and Gynecology Tutorial - Oak Brook, Illinois, November 10, 1995.

129. "Algorithms for the Management Urinary Incontinence": A modern, systematic approach to Diagnosis and Treatment; Retropubic Operations for Stress Incontinence: Patient Selection, Techniques and Outcome; Cystovaginal and Rectovaginal Fistula Repair: Operations, Techniques and Outcomes. Operative Laparoscopy and Urogynecology Course, Steamboat Springs Colorado, February 7-9, 1996.

130. "Contraception" At the Osler Review Course, St. Louis, Missouri, April 21, 1996.

131. "Laparoscopic Bladder Neck Suspension; Vaginal Vault Suspension." at the Advanced Operative Endoscopy Course and Hysteroscopy Workshop, Palo Alto, California, June 1, 1996.

132. "Contraceptive Update" Osler Review Course, Chicago, Illinois, June 18, 1996.

133. "Menstrual Disorders; Urinary Incontinence; Pelvic Pain; Menopausal Syndrome. " Osler Review Course, Lisle, Illinois, July 10, 1996.

134. "Anatomy of the Pelvic Floor and Physiology of Incontinence; Evaluation of Urinary Incontinence and Pelvic Floor Disorders and Open Procedures for Urinary Incontinence. Cincinnati, Ohio, July 26, 1996.

135. "Role of Endoscopy in Reconstructive Pelvic Surgery; Evaluation of Urinary Incontinence and Open Surgical Management of Urinary Incontinence." At the Operative Gynecologic Hysteroscopy and Laparoscopy course Atlanta, Georgia, September 6-7, 1996

136. "An Overview of Urinary Stress Incontinence. " At the American Association of Gynecologic Laparoscopists, Chicago, Illinois, September 27, 1996.

137. "Gynecologic Problems in Surgery." General Surgery Review Course, Chicago, Illinois, October 9, 1996.

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138 "Contraception. " Chicago Area Review Course, Chicago, Illinois, October 16, 1996.

PRESENTATIONS AND INVITED LECTURES (Cont):

139. "Contraception. " Obstetrics and Gynecology Review, Chicago, Illinois, November 6, 1996.

140. "Contraceptive Update." Grand Rounds, Michael Reese Hospital, Chicago, Illinois, January 9, 1997.

141. "Contraceptive Update." Chicago Obstetrics and Gynecology Review, Chicago, Illinois, April 16, 1997.

142. "Contraception; Ectopic Pregnancy; Injections and Antibiotics; HIV and the Woman Patient; Obstetrical Emergencies." At the Obstetrics and Gynecology Review Course, St. Louis Missouri, April 23, 1997.

143. "Urinary Incontinence." "Practical Pearls for Women's Health Care: A Clinical Perspective" At the University of Illinois at Chicago, Illinois, May 17, 1997.

144. "Urinary Incontinence: Evaluation and Open Surgical Repair; Role of Laparoscopy in Pelvic Reconstructive Surgery." At the Laparoscopic Pelvic Surgery Course, Atlanta Georgia, May 23-24, 1997.

145. "Painful Bladder Syndromes." At the 25' Annual Conference for Nurse Practitioners in Women's Health, Milwaukee, Wisconsin, June 11, 1997.

146. "Contraception; Ectopic Pregnancy; Infections and Antibiotics." Arlington Heights, Illinois, June 25, 1997.

147. "Contraceptive Update." Springfield, Illinois, July 24, 1997.

148. "Evaluation and treatment of urinary incontinence; painful bladder syndromes: Interstitial cystitis, urethral syndrome, and sensory urgency; Treating pelvic floor dysfunction" at Advances in Health Care for Women Over 40. Jackson Hole, Wyoming, August 7-8, 1997.

PRESENTED ABSTRACTS:

1. Levy JS, Rosenzweig BA, Kaplan B, et al: Changed criteria for antenatal fetal heart rate testing: A five year single institution experience. Presented at the Eighth Annual Meeting of the Society of Perinatal Obstetricians, February 6, 1988, Las Vegas (Abstract #267).

2. Bergman F, Rotmensch S, Rosenzweig BA, et al: Analysis of Factor VIII complex and Von Willebrand factor multimers in preeclampsia. Presented at the Thirty-Sixth Annual Meeting of the Society for Gynecologic Investigation, March 17, 1989, San Diego (Abstract #277).

3. Thomas S, Karram M, Rosenzweig BA, Bhatia NN: Long-term experience with the Birch procedure: Effects of menopausal status on outcome. Presented at the Thirty-Eighth Annual Meeting of the American College of Obstetricians and Gynecologists, May 9, 1990, San Francisco.

4. Rosenzweig BA, Soffici AR, Thomas S, Bhatia NN: Voiding patterns of patients with cystocele. Presented at the Twelfth Annual Symposium of the Urodynamics Society, May 12, 1990, New Orleans.

5. Rosenzweig BA, Bhatia NN: The use of carbon dioxide laser in urology. Presented at the Eleventh Annual Meeting of the Gynecologic Laser Society, June 10, 1990, Chicago.

6. Rosenzweig BA, Bhatia NN, Hischke D, et al: The psychological profiles of women before and after surgical treatment of stress urinary incontinence. Proceeding of the Twentieth

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Annual Meeting of the International Continence Society, September 12-15, 1990, Aarhus, Denmark.

PRESENTED ABSTRACTS (Cont):

7. Rosenzweig BA, Bhatia NN: Temporal separation of urethral and bladder pressure spikes during cough in women with stress urinary incontinence, urge incontinence and after incontinence surgery. Proceeding of the Twentieth Annual Meeting of the International Continence Society, September 12-15, 1990, Aarhus, Denmark.
8. Rosenzweig BA, Bhatia NN, Hischke D, Thomas S, Nelson AL: The psychological status of women before and after treatment of stress incontinence. Presented at the Eleventh Annual Meeting of the American Uro-Gynecologic Society, November 1, 1990, Tarpon Springs.
9. Rosenzweig BA, Bhatia NN, Nelson AL: Pressure transmission ratio: What do the numbers really mean? Presented at the Eleventh Annual Meeting of the American Uro-Gynecologic Society, November 2, 1990, Tarpon Springs.
10. Rosenzweig BA, Blumenfeld D, Bhatia NN: Incidence of urinary incontinence in asymptomatic women with severe genitourinary prolapse: A rationale for preoperative urodynamic evaluation. Presented at the Thirty-Ninth Annual Meeting of the American College of Obstetricians and Gynecologists, May 7, 1991, New Orleans.
11. Rosenzweig BA, Blumenfeld D, Bhatia NN: Pessary test in the evaluation of detrusor instability in women with genitourinary prolapse. Proceeding of the Twenty-First Annual Meeting of the International Continence Society, October 10-12, 1991, Hannover, Germany.
12. Rosenzweig BA, Blumenfeld D, Bhatia NN: Detrusor instability in women with genitourinary prolapse: Correlation of pessary test with operative results. Presented at the Twelfth Annual Meeting of the American Uro-Gynecologic Society, October 23, 1991, Newport Beach
13. Rosenzweig BA, Bhatia NN, Karram. MM, Blumenfeld D: Management. of recurrent severe stress urinary incontinence using modified suburethral sling procedure: Autologous versus synthetic material. Presented at the Twelfth Annual Meeting of the American Uro Gynecologic Society, October 25, 1991, Newport Beach.
14. Rosenzweig BA, Prins GS, Bolina PS, et al: Steroid receptors of the lower urinary tract in the rabbit. Presented at the Annual Clinical Meeting of the American College of Obstetricians and Gynecologists. May 5, 1993. Washington, DC.
15. Rosenzweig BA, Scotti RJ: The state of resident education in urogynecology. Presented at the CREOG and APGO Annual Meeting. March 2-5, 1994, Nashville.
16. Hopkins S, Rosenzweig B, Maurice J. Laparoscopic Retrieval of an Intraperitoneal Intrauterine Devic. 42nd Global Conference of Minimally Invasive Gynecology. November 2013. Washington DC.

PUBLICATIONS:

BOOK CHAPTERS:

1. Gunning JE, Rosenzweig BA. Evolution of endoscopic surgery. In: White RA, Klein SR, eds. *Endoscopic Surgery*. St. Louis, Mosby-Yearbook, Inc., 1991:3.
2. Bhatia NN, Rosenzweig, BA. The urologically oriented neurological examination. In: Ostergard DR, Bent AE, eds. *Urogynecology and Urodynamics: Theory and Practice*,

Bruce A. Rosenzweig, MD

3rd ed. Baltimore, Williams and Wilkins, 1991:102.

3. Rosenzweig BA. Endoscopy evaluation of the lower urinary tract. In: Walters MD, Karram MM, eds. *Clinical Urogynecology*. St. Louis, Mosby-Yearbook, Inc., 1993:124.

4. Rosenzweig BA. Radiologic studies of the lower urinary tract. In: Walters MD, Karram MM, eds. *Clinical Urogynecology*. St. Louis, Mosby-Yearbook, Inc., 1993:134.

BOOK CHAPTERS (Cont):

5. Lind LR, Rosenzweig BA, Bhatia NN. Urologically oriented neurological examination. In Ostergard Dr. Bent AE, eds. *Urogynecology and Urodynamics: Theory and Practice 4th ed.*, Baltimore, Williams and Wilkins, 1996:99.

6. Maurice JM, Rosenzweig BA. Acute Female Pelvic Pain *Common Surgical Diseases: An Algorithmic Approach, 3rd Edition*, In Press

LETTERS TO THE EDITOR:

1. Levy J, Rosenzweig BA, Blumenthal P: Amnioinfusion for fetal distress. *Am J Obstet Gynecol*, 1986;155:1361.

2. Levy J, Rosenzweig BA: Intubation and resuscitation of meconium-stained newborns. *Resp Care*, 1987;32:130.

3. Levy J, Rosenzweig BA, Blumenthal P: Comparison of uterine activity by nipple stimulation and oxytocin. *Obstet Gynecol*, 1987;70:430.

4. Blumenthal P, Rosenzweig BA: The prophylactic effect of doxycycline on postoperative infection rate after first-trimester abortion. *Obstet Gynecol*, 1988;72:146.

5. Rosenzweig BA: Dynamic urethral pressure profilometry pressure transmission ratio: What do the numbers really mean? Letter (in reply). *Obstet Gynecol*, 1991;78:476.

PUBLISHED ABSTRACTS:

1. Rosenzweig BA, Rader JS, Padleckas R, et al: Correlation of human papillomavirus DNA and presence of atypical squamous cells in Pap smears. *Gynecol Oncol*, 1989;32:115.

2. Rosenzweig BA, Soffici AR, Thomas S, Bhatia NN: Voiding patterns of patients with cystocele. *Neurourol Urodynam*, 1990;9:230.

ORIGINAL ARTICLES:

1. Rosenzweig BA, Rotmensch S, Ressetar A: Term interstitial pregnancy resulting in a live infant. *Obstet Gynecol*, 1988;72:491.

*2. Blumenthal PD, Rosenzweig BA, Levy JS, et al: Ectopic pregnancy prevalence at a tertiary urban obstetrical center: The roles of previous surgery, hospital self-selection and detection bias. *Am J Gynecol Health*, 1988;2:18.

3. Levy JS, Rosenzweig BA, Blumenthal L: Bilateral tubal pregnancies after tubal sterilization. *Obstet Gynecol*, 1988;72:494.

*4. Rosenzweig BA, Rotmensch S, Binette SP, Philippe M: Primary idiopathic polymyositis and dermatomyositis complicating pregnancy: Diagnosis and management. *Obstet Gynecol Surv*, 1989;34:950.

Bruce A. Rosenzweig, MD

5. Rosenzweig BA, Levy JS, Schipiour P, Blumenthal PD: Comparison of the nipple stimulation and exogenous oxytocin contraction stress tests: A randomized prospective study. *J Reprod Med*, 1989;34:950.

6. Rotmensch S, Rosenzweig BA, Philippe M: The impact of the AIDS epidemic on the philosophy of childbirth. *Am J Obstet Gynecol*, 1989; 161:855.

*** Non peer review**

ORIGINAL ARTICLES (Cont):

7. Rosenzweig BA, Seifer DB, Grand WD, et al: Urologic~ injury during vaginal hysterectomy. A case-control study. *J Gynecol Surg*, 1990;6:27.

*8. Rosenzweig BA, Birenbaum DL, Baggish MS: Pelvic inflammatory disease as a complication of carbon dioxide laser surgery of the cervix. *J Gynecol Surg*, 1989;5:117.

9. Baggish MS, Sze EHM, Rosenzweig BA, et al: Direct hysteroscopic observation to document the reasons for abnormal bleeding secondary to submucous myoma. *J Gynecol Surg*, 1989;5:149.

10. Rosenzweig BA, Baggish MS, Sze EHM: Carbon dioxide laser therapy for benign cervical tumors. *J Gynecol Surg*, 1990;6:97.

11. Sze EHM, Rosenzweig BA, Osborne NG, Baggish MS: Catheter-associated bacteriuria following gynecologic surgery. *J Gynecol Surg*, 1989;5:171.

12. Sze EHM, Rosenzweig BA, Birenbaum DL, et al: Excisional conization of the cervix uteri: A five-part review. Parts I and II. *J Gynecol Surg*, 1989;5:235.

13. Sze EHM, Rosenzweig BA, Birenbaum DL, et al: Excisional conization of the uteri: A five part review. Parts III, IV and V. *J Gynecol Surg*, 1989;5:325.

14. Cohn GM, Rosenzweig BA, Adelson MD, Sze EHM: A complication associated with pneumatic compression stocking used for gynecologic surgery. *J Gynecol Surg*, 1989;5:389.

15. Rader JS, Rosenzweig BA, Spirtas R, et al: Atypical squamous cells: A case-series study of the association between Papanicolaou smear and human papillomavirus DNA genotype. *J Reprod Med*, 1991;36:291.

16. Bergman F, Rotmensch S, Rosenzweig BA, et al: The role of von Willebrand factor in preeclampsia. *Thromb Haemostas*, 1991;66:525.

17. Rosenzweig BA, Soffici AR, Thomas S, Bhatia N: Urodynamic evaluation of voiding in women with cystocele. *J Reprod Med*, 1992;37:162.

18. Rosenzweig BA, Bhatia NN: The use of carbon dioxide laser in female urology. *J Gynecol Surg*, 1991;7:11.

19. Rosenzweig BA, Hischke D, Thomas S, et al: Stress incontinence in women: Psychological status before and after treatment. *J Reprod Med*, 1991;36:835.

20. Rosenzweig BA, Bhatia NN: Temporal separation of cough-induced urethral and bladder pressure spikes in women with urinary incontinence. *Urology*, 1992;39:165.

21. Karrarn MM, Rosenzweig BA, Bhatia NN: Artificial urinary sphincter for recurrent-severe stress urinary incontinence in women: Urogynecologic perspective. *J Reprod Med*, 1993;38:791.

22. Rosenzweig BA, Bhatia NN, Nelson AL: Dynamic urethral pressure profilometry pressure transmission ratio: What do the numbers really mean? *Obstet Gynecol*, 1991;77:586.

23. Rosenzweig BA: Neurological control of micturition. *J Gynecol Surg*, 1992;8:59.

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24. Ogundipe A, Rosenzweig BA, Karrarn MM, et al: Modified suburethral sling procedure for the treatment of recurrent or severe stress urinary incontinence. *Surg Gynecol Obstet*, 1992;175:173.

* Non peer review

ORIGINAL ARTICLES (Cont):

25. Rosenzweig BA, Pushkin S, Blumenfeld D, Bhatia NN: Prevalence of abnormal urodynamic test results in continent women with severe genitourinary prolapse. *Obstet Gynecol*, 1992;79:539.

26. Rosenzweig BA: Genitourinary prolapse and lower urinary tract dysfunction. *Int Urogynecol J*, 1993;4:296.

27. Regan MA, Rosenzweig BA: Vulvar carcinoma in pregnancy: A case report and literature review. *Am J Perinatal*, 1993;10:334.

28. Font GE, Brill AI, Stuhldreher PV, Rosenzweig BA: Endoscopic management of incidental cystotomy during operative laparoscopy. *J Urol*, 1993;149:1130.

*29. Marcovici I, Rosenzweig BA, Brill AI, Khan M, Scommegna A: Cervical pregnancy: Case reports and a current literature review. *Obstet Gynecol Surv*, 1994;49:49.

30. Norton P, Karram M, Wall LL, Rosenzweig BA, et al: Randomized double-blind trial of terodiline in the treatment of urge incontinence in women. *Obstet Gynecol*, 1994;84:386

31. Marcovici I, Rosenzweig BA, Brill AI, Scommegna A: Colchicine and post inflammatory adhesions in a rabbit model: A dose response study. *Obstet Gynecol*, 1993;82:216.

32. Baggish, MS, Brill AI, Rosenzweig BA, et al: Fatal acute glycine and sorbitol toxicity during operative hysteroscopy. *J Gynecol Surg*, 1993;9:137.

33. Rosenzweig BA, Bolina PS, Birch L, et al: Location and concentration of estrogen, androgen, and progesterone, and androgen receptors. in the bladder and urethra of the rabbit. *Neurourol Urodynam*, 1995;14:87.

34. Rosenzweig BA, Even AH, Scotti RJ: The state of resident education in urogynecology. *Int Urogynecol J*, 1995;6:18.

*35. Rosenzweig BA, Brill AI: Laparoscopic colposuspension operation, *Pro. J Gynecol Surg*, 1994;10:203.

36. Rosenzweig BA: Severe genital prolapse and its relationship to detrusor instability. *Int Urogynecol J*, 1995; 6:86.

37. Mauck C, Glover L.H., Miller E, Allen S, Archer DF, Blumenthal P, Rosenzweig BA et al: Lea's Shield: A phase 1 study of the safety and efficacy of a new vaginal barrier contraceptive used with and without spermicide. *Contraception*, 1996; 53:329.

38. Rosenzweig BA, Even A, Budnick LE: Observations of scanning electron microscopy detected abnormalities of untreated latex condoms. *Contraception*, 1996; 53:49.

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*** Non peer review**

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312-942-6440 Office
312-942-6438 Fax

To Whom It May Concern:

From Bruce A. Rosenzweig, M.D.

Please note the following fees for expert opinion \$750.00 per hour for review of medical records and conference, \$1,500.00 per hour for deposition, and \$10,000.00 for trial testimony plus travel and hotel expenses. Please forward a **retained amount of \$15,000.00** payable to Dr. Bruce Rosenzweig to be sent with medical records (Tax ID# 201637125). Payment may be mailed to the address listed. Should you have any questions please call the office.

Sincerely,

/Bruce Rosenzweig/
Bruce A. Rosenzweig, M.D.

EXHIBIT B

**Testimonial History
of
Bruce Alan Rosenzweig, M.D.
2009 to Present**

Donald Budke v. Becky Simpson, M.D.
Court Case No. 10CM-CC00085
Missouri Circuit Court, 26th Judicial Circuit

Roxann Comried v. Thomas Getta, M.D., *et al.*
Court Case No. LA CV062272
Linn County District, Cedar Rapids, IA

Barbara Duckworth v. American Medical Systems, Inc.
Court Case No. 201137645
Texas District Court, Harris County, TX

Mary Ann Grady v. Jorge Romero, M.D.
Court Case No. CV-2011-10-5610
Ohio Common Pleas Court, Summit County, OH

Beverly Green v. Fitzgibbon Hospital
Court Case No. 08SA-CV00057
Missouri Circuit Court, 15th Judicial Circuit

Sandra L. Greene v. Lia D. Shorter, M.D., *et al.*
Court Case No. CL10000246-00
Fredericksburg Circuit Court, Fredericksburg, VA

Brooke Hollan v. Daniel Gehlbach, M.D.
Court Case No. 09CV02184
Johnson County District Court, KS

Tammy Jefferson, *et al.* v. Greater Washington Medcenter, LLC
Court Case No. CAL09-15527
Circuit for Prince George's County, MD

Mary King v. Michael Heit, M.D.
Court Case No. 13-CI-003843
Jefferson County, KY

Mary Labbe v. Summa Hospital System
Court Case No. CV-2010-11-7805
Ohio Common Pleas Court, Summit County, OH

Christy McKinney v. Summa Health System
Court Case No. CV-2011-10-5843
Ohio Common Pleas Court, Summit County, OH

Melissa Mills v. Parag Patel, M.D.
Court Case No. 05-CI-02315
Circuit Court, Boone County, KY

Judith Nash v. Kianoush Khaghany, *et al.*
Court Case No. Unknown
Michigan Circuit Court, 38th Judicial Circuit, MI

Deborah O'Donnell v. Antoinette Berkley, M.D.
Court Case No. 000971/2007
Supreme Court of New York, 9th Judicial District NY

Patricia Pater v. Mercy Health System
Court Case No. 10LA000347
Illinois Circuit Court, 22nd Judicial Circuit, IL

Marilyn Pitton, *et al.* v. Kim Josen, M.D., *et al.*
Court Case No. CV2010-050204
Arizona Superior Court, Maricopa County, AZ

Marie Skelnik v. Donald C. Whiteside, M.D.
Court Case No. 08-CVS-3683
Superior Court, Mecklenburg County, IL

Mason Smith v. John Payne, M.D.
Court Case No. 49D04-0511-CT-42869
Marion County Superior, Indianapolis, IN

Noshay v. Northwestern Medical Center
Court Case No. 10 L 004822
Cook County, IL

Tara Mills v. Todd P. Berner, M.D.
Court Case No. Unknown
Virginia

Christine A. Warner v. Thomas W. Hinz
Court Case No. Unknown
Georgia

Lewis v. Ethicon TVT
Case # 2: 12 - CV – 04301
U. S. District Court Southern District of West Virginia
Deposition 11/01/2013

Elizabeth Guterrez v Westlake Hospital et. al
Court No. 09 L 4276
Case No. 2010013165 (Illinois either Cook or Du Page county)
Deposition 11/21/2013

Lewis v Ethicon TVT
Case # 2: 12 - CV – 04301
U. S. District Court Southern District of West Virginia
Trial 02/11/2014

Huskey v. Ethicon TVT-O
Case # 2: 12 – CV – 09972
U. S. District Court Southern District of West Virginia
Deposition 3/25/14

Martinez v AMS and Endo Pharmaceuticals
Cause No. DC-13-13098
District Court of Harris County, Texas
Deposition 3/31/2014

Blankenship & Pugh v Boston Scientific Corp
Case No. 2:13-cv-22906 and 01565
U. S. District Court Southern District of West Virginia
Deposition 6/09/2014

Stamper v The Christ Hospital et al
Case No. A 1205079
Hamilton County, Ohio
Deposition 6/18/2014

Carter v Glazerman, Tampa General Hosp
Case No.: 12-CA-009942
Hillsborough County, Florida
Deposition 7/03/2014

Huskey v Ethicon TVT-O
Case #2: 12 –CV – 09972
U. S. District Court Southern District of West Virginia
Trial Testimony 8/25-26/2014

Corbet v Ethicon TVT-R
Case #291
Docket No. ATL-L-2911-13
Superior Court of New Jersey, Atlantic County
Deposition 8/29/2014

Ramirez v Ethicon TVT-O
Civil Action # 2012-CI-18690
District Court 438th Judicial District, Bexar County, Texas
Deposition 10/11/2014

MDL v CR Bard Align
MDL No. 2187
U. S. District Court Southern District of West Virginia
Deposition 10/29/2014

Covington et al v Bard
MDL No 2187
Case # 2:12 cv-05114
U. S. District Court Southern District of West Virginia
Deposition 10/30/2014

Green et al v Bard
MDL No 2187
Case # 2:13 cv-30766
U. S. District Court Southern District of West Virginia
Deposition 10/31/2014

Tyree et al v Boston Scientific Corp Obtryx
MDL No 2326
Case # 2:12 – cv – 08633
U. S. District Court Southern District of West Virginia
Trial Testimony 11/4/2014

MDL v Boston Scientific Corp Advantage/Lynx
MDL No 2325 – Advantage
U. S. District Court Southern District of West Virginia
Deposition 11/24/2014

Brock et al v Bard
MDL No 2187
Case # 2:12-cv-05114
U. S. District Court Southern District of West Virginia
Deposition 11/29/2014

Carlson et al v Boston Scientific
MDL No 2326
Case # 2:13-cv-5475
U. S. District Court Southern District of West Virginia
Deposition 12/01/2014

Higginbotham et al v Boston Scientific
MDL No 2326
Case # 2:13-cv-5475
U. S. District Court Southern District of West Virginia
Deposition 12/03/2014

Craft et al v Boston Scientific
MDL No 2326
Case # 2:13-cv-04433
U. S. District Court Southern District of West Virginia
Deposition 12/08/2014

Collins et al v Boston Scientific
MDL No 2326
Case # 2:13-cv-11658
U. S. District Court Southern District of West Virginia
Deposition 12/10/2014

Perry v Ethicon Abbrevio
Case No.: 1500-cv-279123 LHB
Superior Court of the State of California
County of Kern
Deposition 12/15/2014

Spohn et al v Bard
MDL No 2187
Case # 2:13 cv-30512
U. S. District Court Southern District of West Virginia
Deposition 12/18/2014

Perry v Ethicon Abbrevio
Case No.: 1500-cv-279123 LHB
Superior Court of the State of California
County of Kern
Trial Testimony 01/29/2015, 02/02/2015, 02/03/2015

Pantoja & Porter v CR Bard
MDL No 2187
Case # 2:14 cv-01353
U. S. District Court Southern District of West Virginia
Deposition 02/09/2015

Kern v Wagner
Case No.: 13-CA-009513
Circuit Court of the Thirteenth Judicial Circuit Hillsborough County, Florida
Civil Division
Deposition 04/02/2015

Acosta et al v CR Bard
MDL No 2187
Case # 2:13 cv-06855
U. S. District Court Southern District of West Virginia
Deposition 05/11/2015

Colletti et al v CR Bard
MDL No 2187
Case # 2:14 cv-11534
U. S. District Court Southern District of West Virginia
Deposition 05/18/2015

Brenner et al v Mentor Obtape
MDL Case No. 2004
U. S. District Court Middle District of Georgia
Colombus Division
Deposition 07/09/2015

Cavness v Ethicon Prosima
Cause No. DC-14-04220
95th District Court
Dallas County, Texas
Deposition 07/13/2015

Sherrer v Boston Scientific and CR Bard
Case No. 1216-CV27879 Division 15

Circuit Court of Jackson County, Missouri at Kansas City
Deposition 8/3/2015
Kilgore v American Medical Systems
Case No.:14CV01312 Division: 14
District Court of Johnson County Kansas
Civil Court Department
Deposition 8/12/2015

Suen et al v Mentor Obtape
MDL Case No. 2004
U. S. District Court Middle District of Georgia
Colombus Division
Deposition 09/10/2015

Cantrell v Ethicon (TVT-R)
Master Docket No. Ber-L-11575-14
Superior Court of New Jersey Law Division – Bergen County
Deposition 09/16/2015

Mullins et al v Ethicon (TVT-R Design Defect)
MDL Master File No. 2:12-MD-02327
U. S. District Court Southern District of West Virginia
Deposition 09/22/2015

Cavness v Ethicon (Prosima)
Cause No. DC-14-04220
95th District Court
Dallas County, Texas
Trial 09/24/2015

Carlson v Boston Scientific (Uphold)
MDL No 2326
U. S. District Court Southern District of West Virginia
U. S. District Court Western District of North Carolina
Trial 10/08/2015

EXHIBIT C

DOCUMENTS

DATE	DOCUMENT	BATES BEG	BATES END
???	Draft? - Gynecare TVT Obturator System Tension-free Support for Incontinence - Instructions for Use	ETH.MESH.03653529	ETH.MESH.03653536
3/2/1981	Guidoin Lab Notebook Page/Image	ETH.MESH.15958524	ETH.MESH.15958524
3/17/1982	Guidoin Lab Notebook Page/Image	ETH.MESH.15958396	ETH.MESH.15958399
3/23/1983	Guidoin Lab Notebook Page/Image	ETH.MESH.15955438	ETH.MESH.15955473
3/25/1983	Guidoin Lab Notebook Page/Image	ETH.MESH.15958410	ETH.MESH.15958432
5/25/1983	Guidoin Lab Notebook Page/Image	ETH.MESH.15958400	ETH.MESH.15958404
8/14/1984	Guidoin Lab Notebook Page/Image	ETH.MESH.15958433	ETH.MESH.15958444
9/27/1984	Guidoin Lab Notebook Page/Image	ETH.MESH.15958408	ETH.MESH.15958409
11/5/1984	Guidoin Lab Notebook Page/Image	ETH.MESH.15958452	ETH.MESH.15958469
11/7/1984	Guidoin Lab Notebook Page/Image	ETH.MESH.15958405	ETH.MESH.15958407
3/11/1985	Guidoin Lab Notebook Page/Image	ETH.MESH.15958445	ETH.MESH.15958451
5/30/1985	Memo N.R. Cholvin to Dr. R.L. Kronenthal, et al. re Protocol for 10 Year In Vivo Study of Monofilament Sutures	ETH.MESH.09746373	ETH.MESH.09746448
9/30/1987	IR Microscopy of Explanted Prolene - Recived from Prof R Guidoin	ETH.MESH.12831391	ETH.MESH.12831404
10/8/1987	Prolene Explants Study Meeting Minutes	ETH.MESH.12831407	ETH.MESH.12831408
11/12/1987	Prolene* Explants Study Meeting Minutes 10/08/1987	ETH.MESH.12831407	
1/20/1988	Guidoin Explant Study notes	ETH.MESH.00004755	ETH.MESH.00004755
1/20/1988	Report: Quebec Explants	ETH.MESH.15144996	ETH.MESH.15144996
8/10/1990	Ten Year <i>In Vivo</i> Suture Study Scanning Electron Microscopy Five Year Report	ETH.MESH.11336474	
3/8/1991	General Program Memorandum #G91-1 from Director, Office of Device Evaluation	N/A	
10/15/1992	Seven year data for ten year Prolene study: ERF 85-219	ETH.MESH.5453719	ETH.MESH.5453727
10/15/1992	Seven year data for ten year Prolene study: ERF 85-219	ETH.MESH.9888187	
1/1/1997	Alex C. Wang "Tension-Free Vaginal Tape (TVT) for Urinary Stress Incontinence - A Preliminary Report"	ETH.MESH.00371572	ETH.MESH.00371573
2/13/1997	Consulting & Technology Agreement between Johnson & Johnson International and Professor Ulf Ivar Ulmsten	ETH.MESH.08696050	ETH.MESH.08696055
2/13/1997	License and Supply Agreement between Johnson & Johnson International and Medscand Medical A.B.	ETH.MESH.8696084	ETH.MESH.8696134
5/16/1997	Report on Expert Meeting	ETH.MESH.12006257	ETH.MESH.12006259
6/13/1997	Ulmsten Preliminary report of Multicentre Study on TVT	ETH.MESH.12009095	ETH.MESH.12009101
8/8/1997	Cytotoxicity Risk Assessment	ETH.MESH.06852120	ETH.MESH.06852129
9/11/1997	Linsky email re TVT (Ulmsten) -510k submission	ETH.MESH.09747728	ETH.MESH.09747728

DOCUMENTS

9/16/1997	PAC Meeting Review - Tension Free Vaginal Tape (TVT) Ulmsten Device	ETH.MESH.09747632	ETH.MESH.09747643
10/1/1997	Linsky C email re Recommendation not to Accelerate TVT Program	ETH.MESH.09747724	ETH.MESH.09747725
10/17/1997	Eriksson Clinical Report	ETH.MESH.00371587	ETH.MESH.00371594
1/11/1998	Presentation: Biocompatibility of ULTRAPRO by Joerg L. Holste, DVM	ETH.MESH.03658577	ETH.MESH.03658577
1/28/1998	FDA 510(k) clearance letter	ETH.MESH.00371496	ETH.MESH.00371594
1/28/1998	Letter from FDA granting 510(k) clearance for TVT	ETH.MESH.371503	
2/18/1998	Liu email chain re Prolene Mesh Redesign	HMRDH_ETH_0013326 1	HMRDH_ETH_001332 62
6/17/1998	Tang email chain re Prolene Mesh Update	ETH.MESH.09266659	ETH.MESH.09266660
6/23/1998	Ellington L email re Prolene Mesh for TVT	ETH.MESH.09266657	ETH.MESH.09266658
7/21/1998	Kaminski email chain re TVT Project Plan	ETH.MESH.10591870	ETH.MESH.10591870
7/30/1998	Kaminski Memo re summary of key point from US Marketing Research Study on TVT	ETH.MESH.00130934	ETH.MESH.00130941
8/17/1998	Rousseau Memo to Lessig re Prolene Mesh Re-Design Project	ETH.MESH.09264945	ETH.MESH.09264946
8/19/1998	Rowan Norrie discussion documents re design of new generation GyneMesh	ETH.MESH.12009027	ETH.MESH.12009035
9/7/1998	Tang email chain re Mesh 3	ETH.MESH.09266668	ETH.MESH.09266671
9/17/1998	Lessig email re PROLENE Mesh Redesign Project	ETH.MESH.07877085	ETH.MESH.07877085
9/23/1998	D Aversa email chain re Prolene Mesh Sheets Research	ETH.MESH.09266465	ETH.MESH.09266466
11/11/1998	R.Rousseau memo to Project Team re Meeting Minutes of Project Planning Meeting	ETH.MESH.9264884	ETH.MESH.9264884
3/30/1999	Gillick email chain re TVT insert	ETH.MESH.00203456	ETH.MESH.00203456
4/8/1999	Toth Memo to Copy Review Team re New Construction PROLENE polypropylene mesh Sales Aid and Demo Device	ETH.MESH.14410703	ETH.MESH.14410741
5/3/1999	Lehe email re Risebericht: TVT-Brainstorming (PD 98/5)	ETH.MESH.11283974	ETH.MESH.11283974
5/4/1999	Toth email chain re New Construction PROLENE polypropylene mesh Pre-Launch Memo w/attachment	ETH.MESH.14410846	ETH.MESH.14410851
6/9/1999	Hoepffner email chain re Trip report -- meeting with Dr. Ulstem	ETH.MESH.11283949	ETH.MESH.11283951
6/18/1999	Angelini email chain re Development Strategy	ETH.MESH.12009276	ETH.MESH.12009277
6/24/1999	Toth, JL Memo to Copy Review Team re TVT Tension-free Vaginal Pate Press Briefing Presentation	ETH.MESH.14411026	ETH.MESH.14411040
7/13/1999	Product Pointer for TVT Tension-free Vaginal Tape	ETH.MESH.03456775	ETH.MESH.03456776
7/14/1999	Hoepffner email re Marketing Requirements for TVT improvement team	ETH.MESH.12009262	ETH.MESH.12009262
8/18/1999	Rousseau email re Samples of PROLENE Mesh	ETH.MESH.09275875	ETH.MESH.09275876
9/13/1999	Lehe email chain re TVT Blue	ETH.MESH.12009257	ETH.MESH.12009257
9/13/1999	E-Mail discussing generations of mesh	ETH.MESH.9275875	

DOCUMENTS

9/15/1999	Major Executive Committee Actions July 20, 1999 through September 15, 1999	ETH.MESH.04193990	ETH.MESH.04193993
10/12/1999	Ulmsten draft Consulting Agreement	ETH.MESH.12002847	ETH.MESH.12002860
10/13/1999	Angelini L email re Ulmsten Consultant Agreement	ETH.MESH.12002845	ETH.MESH.12002845
11/2/1999	TVT Detail Sheet (TVT001R)	ETH.MESH.161444	ETH.MESH.141445
11/15/1999	Ulmsten Consulting Agreement	ETH.MESH.12006763	ETH.MESH.12006783
11/15/1999	J&J Asset Purchase Agreement Medscand	ETH.MESH.5972834	ETH.MESH.5972866
11/15/1999	Consulting Agreement between Ethicon, Inc. and Contape S.A. and Professor Ulf Ivar Ulmsten	ETH.MESH.8692673	ETH.MESH.8692696
11/17/1999	TVT Star PD 99/20 meeting notes.	ETH.MESH.5641096	ETH.MESH.5641098
11/25/1999	Emails between Richard Isenberg, Jochen Hoepffner, Axel Arnaud and Allesandro Rossetti re TVT event Dangerous Procedure/Death	ETH.MESH.3917309	ETH.MESH.3617312
12/2/1999	Biocomp risk assessment GPS revised	ETH.MESH.09346417	ETH.MESH.09346418
12/2/1999	Memo to R. Rousseau re Biocompatibility Risk Assessment for Soft PROLENE Mesh	ETH.MESH.09346419	ETH.MESH.09346420
1/4/2000	Dormier email chain re LcBlanc CME Live on Medscape	ETH.MESH.09273600	ETH.MESH.09273601
4/5/2000	Angleitner email chain re TVT Product complaint w/handwritten notes	ETH.MESH.17661347	ETH.MESH.17661347
4/14/2000	Hellberg communication re Product Complaint Form	ETH.MESH.17661336	ETH.MESH.17661499
4/17/2000	Gynecare TVT Tension-free Support for Incontinence	ETH.MESH.05529274	ETH.MESH.05529275
4/17/2000	Letter from Will Irby (Product Director) to sales representatives Failure to Disclose Adverse Risks/Complications Dangerous Procedure/Tensioning Professional Education/Training	ETH.MESH.5529274	ETH.MESH.5529275
5/26/2000	Biocompatibility Review	ETH.MESH.06852118	ETH.MESH.06852129
5/26/2000	Biocompatibility Review	ETH.MESH.6852118	ETH.MESH.6852129
6/1/2000	Surgeon's Resource Monograph	ETH.MESH.00658177	ETH.MESH.00658198
6/1/2000	Surgeon's Resource Monograph	ETH.MESH.658177	ETH.MESH.658198
6/6/2000	"Meshes in Pelvic Floor Repair - Findings from literature review and conversations/interviews with surgeons" prepared by Brigitte Hellhammer	ETH.MESH.05493965	ETH.MESH.05493999
6/9/2000	Toth Memo re Gynecare TVT Tension-free Support for Incontinence Patient Education Brochure (TVT016)	ETH.MESH.00160612	ETH.MESH.00160625
6/26/2000	TVT 2000626 Gynecare TVT Tension-free Support for Incontinence Patient Education Brochure (TVT016) Patient Kit Letter and Ad template	ETH.MESH.160615	ETH.MESH.160625
7/7/2000	Incontinence/Pelvic Floor Management GYNECARE TVT Tension-free Support for Incontinence 2001 Marketing Plan	ETH.MESH.0137272	ETH.MESH.01137293
7/12/2000	TVT-2 needles Introducer Revision 8	ETH.MESH.01317515	ETH.MESH.01317524

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8/14/2000	TVT Professional Education Tensioning	ETH.MESH.00158559	ETH.MESH.00158590
8/14/2000	Gynecare TVT Professional Education Program	ETH.MESH.158559	ETH.MESH.158590
8/17/2000	Greg Slusser email chain re AUGS lecture/content of discussion	ETH.MESH.10216874	
8/18/2000	Study Justification: Gynecare Clinical Research Program 2001 spreadsheet	ETH.MESH.08793648	ETH.MESH.08793648
8/21/2000	ARnaud A email chain re Pelvic floor repair Procedural Strategy	ETH.MESH.03909708	ETH.MESH.03909713
8/21/2000	Isenberb email re WOW Business Plan -- 2001, Clinical Research	ETH.MESH.08793646	ETH.MESH.08793647
8/21/2000	Emails between Axel Arnaud and Jochen Hoepffner re pelvic floor repair procedural strategy	ETH.MESH.3909708	ETH.MESH.3909713
8/28/2000	Memo Marty Weisberg to Rick Isenberg re discussion with redacted	ETH.MESH.03736578	ETH.MESH.03736578
9/6/2000	Ltt Nilsson from Zauberman re Surgeon Panel	ETH.MESH.09746615	ETH.MESH.09746617
9/22/2000	Memo from J.L. Toth to Copy Review Team re "A three-year follow up of tension free vaginal tape for surgical treatment of the female stress urinary incontinence" Article (TVTO15 - REVIEW FOR REPRINT	ETH.MESH.00143697	ETH.MESH.00143699
9/22/2000	Memo from J.L. Toth to Copy Review Team re "A three-year follow up of tension free vaginal tape for surgical treatment of the female stress urinary incontinence" Article (TVTO15 - REVIEW FOR REPRINT	ETH.MESH.00143700	ETH.MESH.00143702
9/22/2000	Memo from J.L. Toth to Copy Review Team re "A three-year follow up of tension free vaginal tape for surgical treatment of female stress urinary incontinence" Article (TVTO15) - REVIEW FOR REPRINT	ETH.MESH.143697	ETH.MESH.143699
11/1/2000	Memo Marty Weisberg to Rick Isenberg re Complaint	ETH.MESH.03736932	ETH.MESH.03736932
11/30/2000	Emails between Rebecca E. Levine, Ph.D. (Sr. Engineer, R&D) and Jochen Hoepffner re Problem Statements from TVT Brainstorming Meeting.	ETH.MESH.5529653	
1/1/2001	Gynecare TVT Professional Education Slides	ETH.MESH.159636	ETH.MESH.159719
1/16/2001	Dormier email chain re Corporate Product Characterization December Monthly Report	HMESH_ETH_00946830	HMESH_ETH_00946838
2/6/2001	Vypro for Pelvic Floor Repair agenda	HMESH_ETH_02944363	HMESH_ETH_02944364
2/13/2001	Email Axel Arnaud to Dr Uwe re Dr Lucente/TVT Procedure Improvements/Prevention of Overstretching	ETH.MESH.03915380	ETH.MESH.03915380
4/11/2001	Toth Memo re Gynecare TVT Tension-free Support for Incontinence Competitive Mesh Products - Product Pointer	ETH.MESH.00161129	ETH.MESH.00161130

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4/17/2001	Product Pointer: Gynecare TVT Tension-free Support for Incontinence: A Synthetic Sling with Erosion Rates No Higher Than Autologous Slings	ETH.MESH.00161131	ETH.MESH.00161132
4/19/2001	Guidance on Medical Device Patient Labeling; Final Guidance for Industry and FDA Reviewers	ETH.MESH.1203207	ETH.MESH.1203260
4/23/2001	Ulmsten ltr Ostergard re Cannes meeting	ETH.MESH.10181921	ETH.MESH.10181922
5/14/2001	TVT-O Design History Book 5 of 7	ETH.MESH.00222779	ETH.MESH.00223267
5/14/2001	TVT-O Design History Book 1 of 7	ETH.MESH.00259047	ETH.MESH.00259514
5/14/2001	Target Sheet Design History: DH0263-DH0278	ETH.MESH.01317508	ETH.MESH.01317613
5/14/2001	Design History CH1035 (bk2) - DH1036 (bk5)	ETH.MESH.02607272	ETH.MESH.02607814
6/1/2001	Hellhammer email chain re WG: TVT instructions for use	ETH.MESH.05494064	ETH.MESH.05494066
6/1/2001	Angelini L email re TVT improvements	ETH.MESH.12002601	ETH.MESH.12002601
6/4/2001	Emails re TVT recommendation from Dr. Alex Wang Frayed mesh/particle loss	ETH.MESH.3905472	ETH.MESH.3905477
6/6/2001	Weisberg, M email chain re TVT recommendation from Dr. Alex Wang	ETH.MESH.03905472	ETH.MESH.03905477
6/7/2001	TVT 20010607 Gynecare TVT Tension-free Support for Incontinence	ETH.MESH.00144270	ETH.MESH.00144278
6/18/2001	2002-2003 US Marketing Plan for Gynecare TVT Tension-free Support for Incontinence	ETH.MESH.08798099	ETH.MESH.08798110
6/21/2001	TVT Recommendations from Dr. Wang - Meeting Minutes of June 21, 2001	HMESH_ETH.00958003	HMESH_ETH.00958005
6/22/2001	Scientific Advisory Panel on Pelvic Floor Repair Preliminary Minutes	ETH.MESH.02089392	ETH.MESH.02089399
6/26/2001	Luscombe email chain re TVT recommendations from Dr. Wang	HMESH_ETH_00958014	HMESH_ETH_00958015
6/27/2001	TVT 20010607 Gynecare TVR Tension-free Support for Incontinence Patient Brochure (Resubmission of materials per FDA requirement)	ETH.MESH.144270	ETH.MESH.144278
7/3/2001	Presentation: TVT Sales Force Update @ Divisional Meeting	ETH.MESH.00144304	ETH.MESH.00144331
7/6/2001	Dormier E email chain re Vypro vs Soft Prolene Mesh for Pelvic Floor Repair	ETH.MESH.17606501	ETH.MESH.17606502
8/2/2001	5-Year Press Release Draft: Long-term Data Proves Safety and Efficacy of GYNECARE TVT Tension-free Support Treating Stress Urinary Incontinence	ETH.MESH.00764323	ETH.MESH.00764325
8/15/2001	Luscombe B email chain re Aug 11 program	ETH.MESH.00864131	ETH.MESH.00864133
9/28/2001	2002 US Marketing Plan for TVT	ETH.MESH.09306898	ETH.MESH.09306910
10/1/2001	New Products Development Gynecare Products by Axel Arnaud	ETH.MESH.03909721	ETH.MESH.03909733
10/12/2001	Memo by Lynn Hall re Summary of Findings and Next Steps from 10.12.01 TVT DTC Focus Groups	ETH.MESH.1217285	ETH.MESH.1217288
10/26/2001	K012628 TVT Blue System and Accessory TVT-AA	ETH.MESH.748310	ETH.MESH.748450

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12/6/2001	TVT Sales Aid (TVT041) 5 Years of Proven Performance	ETH.MESH.339437	ETH.MESH.339442
1/16/2002	Luscombe email re ALERLT!!! Professional Ads for GYNECARE TVT !!!!! w/attachments	ETH.MESH.00029963	ETH.MESH.00029966
1/28/2002	Corporate Product Characterization - Comparison of Particle Characteristics of Clear and 50% Blue PROLENE Mesh of TVT Device	ETH.MESH.02613804	ETH.MESH.02613805
1/28/2002	Particle Release Characteristics of Clear and Blue TVT Mesh Corporate Product Characterization	ETH.MESH.04384185	ETH.MESH.04384188
3/28/2002	Letter from Howard Zauberman (Ethicon) to Mr. Jan Johansson (Director, EuroSund Medical AB)	ETH.MESH.08695896	ETH.MESH.08695896
4/25/2002	DDSA Re-Evaluation for TVT	ETH.MESH.01317510	ETH.MESH.01317514
4/25/2002	Email Ettore Carino to Kimberly Mullarkey re FW: DTC Review	ETH.MESH.08793552	ETH.MESH.08793553
5/1/2002	"Second Generation TVT" by Axel Arnaud	ETH.MESH.03907468	ETH.MESH.03907469
6/7/2002	Email Richard Isenberg to Greg Jones, et al. re Dr Alex Wang, Taiwan--Reports of "tape rejection" with TVT	ETH.MESH.00409674	ETH.MESH.00409675
6/7/2002	Emails Richard Isenberg to Dr Wang re concerns for patient safety	ETH.MESH.03735432	ETH.MESH.03735433
6/7/2002	Emails from Richard Isenberg (Director of Medical Affairs, Gynecare Worldwide) re Dr. Alex Wang, Taiwan - Reports of "tape rejection" with TVT	ETH.MESH.409674	ETH.MESH.409675
6/10/2002	Email Mark Yale re Wang's rejections	ETH.MESH.03483690	ETH.MESH.03483693
6/26/2002	Gynecare TVT Tension-free Support for Incontinence - Tips for Speaking with your Physician	ETH.MESH.158082	
6/28/2002	Lawler T email re Polypropylene Mesh	ETH.MESH.01264260	ETH.MESH.01264260
7/2/2002	Corrective/Preventive Action TVT Tape	ETH.MESH.05961197	ETH.MESH.05961203
7/2/2002	Corrective/Preventive Action TVT Tape	ETH.MESH.05961204	ETH.MESH.05961211
7/9/2002	FDA Communication re 522 Prosima	ETH.MESH.04927339	ETH.MESH.04927340
7/18/2002	Isenbert R Note to File re TVT associated Obturator Nerve Syndrome Complaint	ETH.MESH.03736538	ETH.MESH.03736539
9/11/2002	Corrective/Preventive Action TVT Tape	ETH.MESH.05961212	ETH.MESH.05961234
9/16/2002	Email Shannon Campbell to Shelley Copeland, et al. re Ft. Worth Advanced TVT dinner feedback	ETH.MESH.11773498	ETH.MESH.11773499
9/27/2002	Letter to Dr. James Meeuwesen of Pueblo, CO from Scott Jones	ETH.MESH.00030025	ETH.MESH.00030026
9/27/2002	Letter to Dr. James Meeuwesen of Pueblo, CO from Scott Jones (sales rep)	ETH.MESH.30025	
10/4/2002	Rejection of Polypropylene Tape After the Tension-Free Vaginal Tape (TVT) Procedure by Alex C. Wang, MD	ETH.MESH.00409657	ETH.MESH.00409658
10/4/2002	Report: Visit to Pr Jean de Leval	ETH.MESH.03910208	ETH.MESH.03910210
10/13/2002	Emails between Martin Weisberg and Axel Arnaud re Soft Prolene and attached Clinical Expert Report: Prolene Soft (Polypropylene) Mesh	ETH.MESH.3910183	ETH.MESH.3910193

DOCUMENTS

10/14/2002	"Confidential - Trans-obturator TVT - Procedure In-Out" by Axel Arnaud Product Defect	ETH.MESH.3907327	ETH.MESH.3907330
10/15/2002	Arnaud, A; Weisberg email chain originating 09/20/2002 re Soft Prolene " . . . wise to be elusive on warnings . . . "	ETH.MESH.3910175	ETH.MESH.3910177
10/16/2002	TVT 20021016 TVT - Freedom From Stress Urinary Incontinence	ETH.MESH.2169504	ETH.MESH.2619511
10/17/2002	Memo to Jacqueline Russo from Ogilvy Public Relations Worldwide re Dr. Donnica Moore Opportunity Analysis and Recommendation	ETH.MESH.766347	ETH.MESH.766349
10/23/2002	Univ De Leige, Centre Hospitalier Universitaire De Liege and Ethicon Licensing Agreement	ETH.MESH.03918253	ETH.MESH.03918264
10/31/2002	Emails between Martin Weisberg and Mark Sumeray (VP Clinical Trials) re Dr. Wang's proposal to perform histological and immunohistochemical study on biopsies taken from women with tape erosion	ETH.MESH.8793207	ETH.MESH.8793210
11/26/2002	Axel Arnaud email chain re Mini TVT - Mesh adjustment	ETH.MESH.3910418	
11/26/2002	Weisberg email chain originating 11/22/2002 re Mini TVT mesh adjustment - "... overtension is not possible and that tension free placement of the tape is not critical. . . "	ETH.MESH.3917375	ETH.MESH.3917378
12/3/2002	Email Martin Weisberg to Mark Sumeray et al. re Prolene rejection	ETH.MESH.00409670	ETH.MESH.00409670
12/13/2002	Marketing Plan TVT-O	ETH.MESH.3918352	
12/27/2002	Customer Initiated Research Grant Request (Wang)	ETH.MESH.409659	ETH.MESH.409663
1/9/2003	Corrective/Preventive Action TVT Tape	ETH.MESH.05961304	ETH.MESH.05961315
1/27/2003	DTC Focus Group Summary	ETH.MESH.00766975	ETH.MESH.00766976
1/31/2003	Tracey M Trip Report	ETH.MESH.01808311	ETH.MESH.01808318
2/5/2003	Tracey M email re Trip Report Format Mulberry 22Jan2003	ETH.MESH.01808310	ETH.MESH.01808310
2/13/2003	Presentation - Ultrasonic Slitting of TVT Mesh Technical Review	ETH.MESH.06866920	ETH.MESH.06866920
2/14/2003	Due Diligence Growth Opportunity Outline re Project Mulberry Next generation TVT	ETH.MESH.06873447	ETH.MESH.06873458
2/18/2003	Universite de Liege and Ethicon Licensing Agreement	ETH.MESH.15363068	ETH.MESH.15363085
2/20/2003	Arnaud A email chain re TVT complications (an Prof. Häusler)	ETH.MESH.03911107	ETH.MESH.03911108
2/20/2003	Strategic Plan Challenge	ETH.MESH.4205632	ETH.MESH.4205636
2/28/2003	Cirelli - Histological evaluation and Comparison of Mechanical Pull Out Strength of Prolene Mesh and Prolene Soft Mesh in a Rabbit Model	ETH.MESH.01222617	ETH.MESH.01222654
3/18/2003	Osoris M email re International Convention Suggestions	ETH.MESH.00581482	ETH.MESH.00581482

DOCUMENTS

3/20/2003	Strategic Plan Challenge	ETH.MESH.04205632	ETH.MESH.04205636
3/26/2003	Arnaud A email chain re Mulberry	ETH.MESH03919404	ETH.MESH03919405
4/8/2003	Notes from team meeting	ETH.MESH.858080	
4/10/2003	April 10, 2003 meeting minutes from Project Leader Dan Smith	ETH.MESH.00858110	ETH.MESH.00858111
4/14/2003	Smith,D email chain re Mulberry update	ETH.MESH.00260591	ETH.MESH.00260592
4/30/2003	TVOT Meeting Report	ETH.MESH.03934952	ETH.MESH.03934967
5/13/2003	Memo from Anthony Powell (VP, Sales) and Marianne Kaminski (Dir. of PE and Relations) to Gynecare	ETH.MESH.00030098	ETH.MESH.00030098
5/13/2003	Memo from Anthony Powell (VP, Sales) and Marianne Kaminski (Dir. of PE and Relations) to Gynecare Continence Health Sales Team re GYNECARE TVT Physician Training Policy	ETH.MESH.30098	
5/15/2003	Emails Brian Luscombe to Axel Arnaud et al. re: De Leval Publication	ETH.MESH.03918552	ETH.MESH.03918553
5/29/2003	Study spreadsheet	ETH.MESH.00863841	ETH.MESH.00863842
5/29/2003	DHF 25 1-323 CE Mark of TVT - AA Kit.pdf	ETH.MESH.02222437	ETH.MESH.02222656
6/6/2003	LeTreguilly L email chain re TVT Serious complication	ETH.MESH.03907853	ETH.MESH.03907854
6/6/2003	Emails between Sascha Blessin (Sr. Marketing Mng., Gynecare Europe/Germany) and Laure Le Treguilly (Gynecare Marketing Mng.) re TVT - Serious complication Dangerous Procedure/Death	ETH.MESH.3907853	ETH.MESH.3907854
6/11/2003	Russo-Jankewicz email re Stressful Secrets press release crosses wire	ETH.MESH.00764215	ETH.MESH.00764216
6/19/2003	Eltrasonic Slitting of TVT Mesh presentation	ETH.MESH.00586018	ETH.MESH.00586019
6/20/2003	Leibowitz Tensile Properties, Morphology Test Report	ETH.MESH.01279975	ETH.MESH.01279977
6/20/2003	Leibowitz Tensile Properties, Morphology Test Report	ETH.MESH.05442881	ETH.MESH.05442883
6/24/2003	Toddywala R email re Project Mulberry	ETH.MESH.02180737	ETH.MESH.02180737
6/30/2003	Presentation: Marketing Plan VOC by Boris Batke Project Edelweiss	ETH.MESH.05585033	ETH.MESH.05585053
7/7/2003	Email from Brian Luscombe re "Urethral erosion may occur with any sling material" Article (TVT063)	ETH.MESH.30372	ETH.MESH.30373
7/9/2003	Email Martin Weisberg to Terry Courtney re TVT question	ETH.MESH.03715978	ETH.MESH.03715980
7/11/2003	Email Brian Luscombe to Steve Bell, et al. re Ulmsten opinion on Mulberry	ETH.MESH.06884249	ETH.MESH.06884250
7/17/2003	Arnaud email re Mulberry IFU	ETH.MESH.00865147	ETH.MESH.00865147
7/18/2003	Email Brian Luscombe to Dan Smith et al. re Design Validation	ETH.MESH.00864085	ETH.MESH.00864087
7/21/2003	Ciarrocca email chain re Gynemesh holding force in tissue	ETH.MESH.03919143	ETH.MESH.03919144
7/21/2003	Email Janice Burns to Dan Smith, et al. RE: Design Validation	ETH.MESH.06880021	ETH.MESH.06880023
7/24/2003	Smith D email chain re TOVT developments	ETH.MESH.00864101	ETH.MESH.00864102

DOCUMENTS

8/8/2003	Email from Laura Angelini re Transient Leg Pain with MULBERRY		
8/14/2003	Kammerer G email chain re Aug 11 program	ETH MESH 01220661	ETH MESH 01220663
8/15/2003	Email Brian Luscombe re Mulberry Final DRAFT #1	ETH.MESH.00260739	ETH.MESH.00260744
8/18/2003	Kammerer email chain re TVT Mesh Fraying	ETH.MESH.01220693	ETH.MESH.01220697
8/18/2003	Emails re Dr. Alex Wang's complaints re frayed and uneven mesh	ETH.MESH.1220693	
8/21/2003	Cosson, et al, <i>Mechanical properties of synthetic implants used in the repair of prolapse and urinary incontinence in women: which is the ideal material?</i> Int Urogynecol J (2003) 14: 169-178	ETH.MESH.15598	ETH.MESH.15607
8/25/2003	Email Martin Weisberg to Dan Smith, et al. re Mulberry Final Draft #1	ETH.MESH.03715869	ETH.MESH.03715876
9/6/2003	Emails between Martin Weisberg and Dr. Peggy Norton re TVT Underreporting of complications Professional Education/Training	ETH.MESH.3738466	ETH.MESH.3738467
9/8/2003	Arnaud A email chain re TVT complication	ETH.MESH.03928696	ETH.MESH.03928697
10/1/2003	Gynecare TVT AUGS & Competitive Update - copy review submission form	ETH.MESH.14415287	ETH.MESH.14415309
10/2/2003	de Leval, J, "Novel Surgical Technique for the Treatment of Female Stress Urinary Incontinence: Transobturator Vaginal Tape Inside-Out"	ETH.MESH.06880472	ETH.MESH.06880478
10/2/2003	Arnaud email re Pr de LEVAL expenses	ETH.MESH.15928345	ETH.MESH.15928345
10/23/2003	Design Input Strategy Project Mulberry by Dan Smith and Janice Burns	ETH.MESH.259269	ETH.MESH.259274
10/25/2003	Letter from Martin Weisberg (Director, Medical Affairs, Gynecare) - 7 Year Data Indicates Strong Continued Safety and Effectiveness For GYNECARE TVT Tension-free Support for Incontinence	ETH.MESH.524444	ETH.MESH.524445
10/30/2003	Presentation: TVT Patent Portfolio by Andrea Slater-Tomko	ETH.MESH.5236223	ETH.MESH.5236255
11/18/2003	Weisberg Memo re Mesh Fraying for TVT Devices	ETH.MESH.00541379	ETH.MESH.00541380
11/18/2003	Memo by Martin Weisberg re Mesh Fraying for TVT Devices Inadequate testing	ETH.MESH.541379	ETH.MESH.541380
11/20/2003	Ultrasonic Slitting of Prolene Mesh for TVT Feasibility Study	ETH.MESH.01222584	ETH.MESH.01222705
11/20/2003	Ultrasonic Slitting of Prolene Mesh for TVT Feasibility Study	ETH.MESH.02614396	ETH.MESH.02614399
11/26/2003	Emails between Martin Weisberg and Barbara McCabe re leVal	ETH.MESH.3715571	ETH.MESH.3715573
12/8/2003	Attachment V 510(k) Summary Gynecare TVT Obturator	ETH.MESH.00019863	ETH.MESH.00019924

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12/9/2003	3.4.4 DDSA version 0 - Memo Gary Borkes to DHF for the Gynecare TVT-Obturator re TVT-O Version 0 Design Risk Assessment Evaluation	ETH.MESH.00222366	ETH.MESH.00222395
1/1/2004	Only Gynecare TVT Has Long-term Results You Can See	ETH.MESH.00160813	ETH.MESH.00160821
1/1/2004	2004 Performance & Development Plan for Patricia Hojnoski	ETH.MESH.7931874	ETH.MESH.7931886
1/7/2004	TVT-O IFU (1/7/2004-3/4/2005)	ETH.MESH.02340829	ETH.MESH.02340901
1/16/2004	Smith D email re Dedications	ETH.MESH.06164409	ETH.MESH.06164410
1/22/2004	Presentation: Sales Training Launch Meeting Gynecare TVT Obturator System	ETH.MESH.00857821	ETH.MESH.00857923
1/29/2004	Gynecare TVT Introduction to cross train the Uterine	ETH.MESH.05793690	ETH.MESH.05793693
2/19/2004	Smith D email re TVT-O recognition Submission	ETH.MESH.06892171	ETH.MESH.06892172
2/27/2004	Smith D email chain re 2 TVT Complaints concerning allegedly brittle mesh	ETH.MESH.00863391	ETH.MESH.00863393
3/1/2004	Burns email chain re Mulberry IFU	ETH.MESH.00866317	ETH.MESH.00866318
3/2/2004	Owens C email chain re Reminder on BLUE mesh	ETH.MESH.00865322	ETH.MESH.00865323
3/2/2004	Burns email chain re Remainder on BLUE mesh!	ETH.MESH.13204333	ETH.MESH.13204334
3/3/2004	Copy Review Submission Form - Inside Gynecare Vol II, #5	ETH.MESH.14416182	ETH.MESH.14416221
3/9/2004	Luscombe B email chain re Complaint TVT-O	ETH.MESH.00863405	ETH.MESH.00863407
3/10/2004	TVT 20040310 What you Can do about it... TVT-Stress Urinary Incontinence in Women	ETH.MESH.02619601	ETH.MESH.02619616
3/17/2004	Gynecare Copy Review Submission Form submitted by Giselle M. Bonett re Gynecare Gynemesh PS	ETH.MESH.14416076	ETH.MESH.14416081
3/29/2004	de Leval J memo	ETH.MESH.02180759	ETH.MESH.02180761
4/14/2004	Copy Review Submission Form - MoniTorr, TVT-O, CORLINK, ProPen, MultiPass	ETH.MESH.14416898	ETH.MESH.14416959
4/14/2004	TVT sales piece (TVT041R3) Only Gynecare TVT Has Long-Term Results You Can See...and Believe Pore size Fibrotic bridging/scar plate/contraction/shrinkage Chronic inflammatory response	ETH.MESH.658058	ETH.MESH.658065
4/19/2004	LIMS Project #: BE-2004-912 Study Report	ETH.MESH.00158286	ETH.MESH.00158288
4/19/2004	Kammerer G email re Ultrasonic Slitting of Prolene Mesh for TVT	ETH.MESH.00584811	ETH.MESH.00584813
4/27/2004	LIMS Project #: BE-2004-916	ETH.MESH.00862206	ETH.MESH.00862208
5/4/2004	Schiaparelli J email re Marlex Experience	ETH.MESH.05918776	ETH.MESH.05918776
5/21/2004	Email from David Robinson MD to Dan Smith regarding deLeval's Babcock technique	ETH.MESH.864413	
6/30/2004	Leibowitz email re Comparison of TVT Mesh to Meshes from Competitive Devices	ETH.MESH.00863692	ETH.MESH.00863694
7/21/2004	Emails between Axel Arnaud, Janice Burns and Olivia Derwin (Acct. Manager, Gynecare) re TVT Erosion?	ETH.MESH.3910799	ETH.MESH.3910800

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7/22/2004	Email Walji to Bogardus, et al. re ICS / Paris - Gala Invitee List	ETH.MESH.02201463	ETH.MESH.02201467
8/16/2004	Email James McDivitt to Thomas Barbolt re Autoclaving PROLENE	ETH.MESH.05456117	ETH.MESH.05456118
8/17/2004	Email from Dan Smith to Katrin Elbert re IFU changes	ETH.MESH.01814740	ETH.MESH.01814741
8/17/2004	Burns J email chain re TVT-O	ETH.MESH.06881576	ETH.MESH.06881580
8/18/2004	Mahar K email re Dr. Jensen Follow UP	ETH.MESH.06884516	ETH.MESH.06884517
8/27/2004	Email Marianne Kaminski to Amy Vie, et al. re 2004 budget - PE August adjustments	ETH.MESH.05795299	ETH.MESH.05795300
9/7/2004	Walji email chain re Pelvic Floor Monthly - August Report - Next Gen Materials Progress	ETH.MESH.00681364	ETH.MESH.00681366
9/11/2004	Gynecare University Program Las Vegas, Nevada	ETH.MESH.08107153	ETH.MESH.08107155
9/16/2004	Campbell, S email chain re Ongoing TVT-O Action Items	ETH.MESH.00864503	ETH.MESH.00864507
9/16/2004	Campbell email chain re Ongoing TVT-O Action Items	ETH.MESH.06884728	ETH.MESH.06884732
9/23/2004	"Professional Education for GYNECARE TVT Physician Training" updated draft by Marianne Kaminski	ETH.MESH.03624321	ETH.MESH.03624322
9/24/2004	Gyncecare Mega Course Uterine Health Urodynamics Incontinence and Pelvic Floor Repair and the OB/GYN Surgeon, Urogynecologist and Urologist	ETH.MESH.05795309	ETH.MESH.05795315
10/7/2004	Sales School Presentation: Gynecare Professional Relations and Professional Education "Educating Customers Worldwide to improve the lives of women!"	ETH.MESH.00031538	ETH.MESH.00031560
10/18/2004	Cancellation Agreement between Ethicon, Inc., Contape S.A., and the estate of Professor Ulf Ivar Ulmsten	ETH.MESH.8692670	ETH.MESH.8692672
11/1/2004	Smith D email re Update from Oct 27 cadaver lab	ETH.MESH.05548122	ETH.MESH.05548123
11/2/2004	Email from Patty Lancos to Manuel Castro and Dan Smith re FDA Prep	ETH.MESH.01813975	ETH.MESH.01813978
11/5/2004	MedWatch Report	ETH.MESH.03589219	ETH.MESH.03589220
11/9/2004	Gynecare - Value Proposition Report Porject TVTx	ETH.MESH.06705963	ETH.MESH.06705976
11/10/2004	Telefax from Basso Sibyll to David Menneret (Complaint investigator/Regulatory contact) re Dr. Eberhard	ETH.MESH.2180828	ETH.MESH.2180830
11/10/2004	Presentation by Boris Batke (Ethicon R&D): The (clinical) argument of lightweight mesh in abdominal surgery	ETH.MESH.5479411	
11/12/2004	Email from David Menneret to Dan Smith and others re Mesh Fraying: DR. EBERHARD letter	ETH.MESH.2180826	ETH.MESH.2180827
11/12/2004	Translation of PD Doctor Eberhard's letter of 18.10.04	ETH.MESH.2180833	
11/30/2004	7 year Data Press Release New Study Shows Minimally-Invasive Surgery for Female Incontinence Offers Good Long-Term Cure Rates	ETH.MESH.155598	ETH.MESH.155600

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12/6/2004	Development Contract TVT-Next (TVT _x)	ETH.MESH.01217673	ETH.MESH.01217690
12/8/2004	TVT 20041208 Gynecare TVT Tension-free Support for Incontinence Patient Brochure reprint /Robin Osman	ETH.MESH.08003197	ETH.MESH.08003212
12/10/2004	Emails between Steve Bell, Kevin Mahar and Dan Smith re VOC on Laser cut mesh - underreporting of complications	ETH.MESH.1811770	ETH.MESH.1811772
12/14/2004	Leibowitz B Memo re Comparison of Laser-Cut and Machine-Cut TVT Mesh to Meshes from Competitive Devices (BE-2004-1641)	ETH.MESH.01809080	ETH.MESH.01809081
1/3/2005	2005 Variable Compensation Plan Sales Representative	ETH.MESH.05768705	ETH.MESH.05768712
1/5/2005	Email Laura Angelini to Ronnie Toddywala, et al. re Important Laser cut mesh Update	ETH.MESH.00440005	ETH.MESH.00440007
1/11/2005	Email Katrin Elbert re TVT-O IFU change	ETH.MESH.00261818	ETH.MESH.00261818
1/17/2005	Kammerer email re Presentation #1	ETH.MESH.00585220	ETH.MESH.00585220
1/18/2005	Hojnoski Personnel File	ETH.MESH.07931874	ETH.MESH.07931886
1/19/2005	Presentation: Mechanical vs. "Machine"-cut Mesh	ETH.MESH.02248778	ETH.MESH.02248778
1/27/2005	Smith email re TVT-U	ETH.MESH.05553782	ETH.MESH.05553782
1/28/2005	Carino email chain re Recommendations for Non-Sales and Marketing Glamour Trip Award	ETH.MESH.08792936	ETH.MESH.08792938
1/30/2005	Castillo email chain re Oscar -- The latest fiasco	ETH.MESH.11474337	ETH.MESH.11474337
2/1/2005	Presentation: TVT Bonnie Blair Campaign	ETH.MESH.00524907	ETH.MESH.00524907
2/2/2005	TVT Mailers for Physicians	ETH.MESH.00162420	ETH.MESH.00162421
2/2/2005	Gynecare TVT Mesh brochure copy review submission form	ETH.MESH.14410478	ETH.MESH.14410484
2/11/2005	TVT IFU through	ETH.MESH.02340471	ETH.MESH.02340503
2/16/2005	Copy review submission form - Hernia ad; Proceed Mesh. ULTRAPRO mesh and PROLENE hernia system	ETH.MESH.14409737	ETH.MESH.14409741
2/28/2005	Everett J Summary Memo for Revision C of the Gynecare PROLIFT Device Design Safety Assessment	ETH-03531	ETH-03567
3/1/2005	Email Charlotte Owens to Carol Holloway re Medical Review file #30005136	ETH.MESH.03574916	ETH.MESH.03574919
3/10/2005	Berger L Itt Wallingford J re Unknown TVT Ref #3005146	ETH.MESH.03499528	ETH.MESH.03499529
3/10/2005	Next Generation Mesh Discussion	ETH.MESH.05245427	ETH.MESH.05245428
3/15/2005	Oldelehr M email chain re Kalamazoo TVT Business at Risk	HMESH_ETH_01876389	HMESH_ETH_01876393
3/24/2005	Hunsicker email chain re ICS Submission	ETH.MESH.06828907	ETH.MESH.06828909
4/5/2005	Email Charlotte Owens to Carin Rassier re Complaint 30005255	ETH.MESH.03575061	ETH.MESH.03575061
4/8/2005	Email re: Gynemesh Training	ETH.MESH.10210051	ETH.MESH.10210057
4/12/2005	Kammerer, G email chain re Ultrapro	ETH.MESH.03915588	ETH.MESH.03915590
4/13/2005	TVT 20040413 Gynecare TVT Tension-free Support for Incontinence Patient Education Brochure/Robin Osman	ETH.MESH.00658421	ETH.MESH.00658429

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4/13/2005	Barbara McCabe email re Sheath Sales Tool	ETH.MESH.00994917	ETH.MESH.00994918
4/13/2005	Sunoco C4001 Polypropylene Homopolymer - MSDS	ETH.MESH.02026591	ETH.MESH.02026595
4/13/2005	Corporate Product Characterization Protocol to Evaluate Elongation, Particle Loss and Flexural Rigidity of TVT U PROLENE Mesh Laser-Cut vs Mechanical-Cut Version 1	ETH.MESH.02614599	ETH.MESH.02614603
4/13/2005	Holste, J email chain re Ultrapro	ETH.MESH.04020134	ETH.MESH.04020137
4/13/2005	Barbolt, T email chain re Ultrapro	ETH.MESH.05469908	ETH.MESH.05469912
4/13/2005	Emails Marianne Kaminski to Paul Parisi, et al. re Q1 PE results REVISED	ETH.MESH.05795322	ETH.MESH.05795324
4/13/2005	TVT 20050413 Gynecare TVT Tension-free Support for Incontinence Patient Education Brochure/Robin Osman	ETH.MESH.658421	ETH.MESH.658429
4/13/2005	Barbara McCabe email re Sheath Sales Tool	ETH.MESH.994917	
4/14/2005	Toddywala, R email chain re Ultrapro	ETH.MESH.03915567	ETH.MESH.03915572
4/29/2005	Komamycky P email chain re Bio compatibility samples	ETH.MESH.05549696	ETH.MESH.05549700
5/5/2005	Seppa K Memo re Performance Evaluation of TVT U Prolene Mesh: Mechanical Cut versus Laser Cut Study (LIMS#BE-2005-1920) Version 3	ETH.MESH.06696367	ETH.MESH.06696379
5/6/2005	London Brown A email re Laser-cut Mesh	ETH.MESH.00526473	ETH.MESH.00526474
5/25/2005	TVT Retropubic Issue Report No. 30005181	ETH.MESH.02627466	ETH.MESH.02627466
6/1/2005	Oldelehr email re gynecology vs urology	ETH.MESH.08107933	ETH.MESH.08107933
6/6/2005	Zaddem V email chain re MINT: 6/2/05 Materials Advisory meeting minutes	ETH.MESH.02020712	ETH.MESH.02020713
6/28/2005	Objectives for Jennifer - May-August	ETH.MESH.19356913	ETH.MESH.19356915
7/19/2005	Clinical Study Agreement between Dr. Douglas Grier and Ethicon	ETH.MESH.00412260	ETH.MESH.00412269
7/25/2005	Pariente, J-L, "An independent biomechanical evaluation of commercially available suburethral slings," <u>Issues in Women's Health</u> , 2003; 9-12	ETH.MESH.1221055	ETH.MESH.1221058
8/16/2005	London Brown A email re TVT Laser Cut Mesh	ETH.MESH.00525573	ETH.MESH.00525573
8/23/2005	Draft Clinical Expert Report Gynecare TVT Secur System by Martin Weisberg, Senior Medical Director	ETH.MESH.03905059	ETH.MESH.03905072
8/23/2005	Email Paula Evans to Sungyoon Rha et al. re TVT Laser Cut Value Proposition and Forecast	ETH.MESH.04985249	ETH.MESH.04985252
8/23/2005	Clinical Expert Report Gynecare TVT Secur System by Dr. Owens' Report	ETH.MESH.01037447	ETH.MESH.01037455
8/24/2005	Gynecare TVT Professional Education Slides	ETH.MESH.00525322	ETH.MESH.00525400
8/26/2005	TVT Obturator Complaint Note to File	ETH.MESH.03736967	ETH.MESH.03736968
8/29/2005	Physician form letter	ETH.MESH.12933182	ETH.MESH.12933183
9/1/2005	Consulting Agreement B-1 between Brian J. Flynn and Ethicon	ETH.MESH.03605398	ETH.MESH.03605402
9/20/2005	Gynecare - Amendment to design validation study Gynecare TVT Secur System	ETH.MESH.04385375	ETH.MESH.04385376

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10/3/2005	APilotStudyoftheGynecareTVTSecurSystem(Tension-freeS	ETH.MESH.00538202	ETH.MESH.00538242
10/12/2005	Letter from Carol Holloway (Product Complaint Analyst) to Herve Fornier (Ethicon France) re TVT tape particles	ETH.MESH.3535750	
10/18/2005	Gynecare - Amendment 2 to design validation study Gyne	ETH.MESH.05473737	ETH.MESH.05473739
10/31/2005	Presentation: Investigator Initiated Study Process by Kimberly Hunsicker, MSN, CRNP (Regional Manager, Clinical Operations) - Inadequate testing	ETH.MESH.311832	ETH.MESH.311848
11/4/2005	Rousseau, R email chain re Gynemesh PS w/Monocryl	ETH.MESH.09268506	ETH.MESH.09268508
11/16/2005	Email from Carolyn Brennan (Project Manager, Worldwide Customer Quality) re Updated TVT and TVT-O Complication Rates 11-15-05	ETH.MESH.875647	ETH.MESH.875649
11/18/2005	Emails between Carolyn Brennan (Project Manager, Worldwide Customer Quality), Patricia Hojnoski (Regulatory Affairs), Martin Weisberg (Senior Medical Director) and Dan Smith (Gynecare R&D) re Updated TVT and TVT-O Complication Rates 11-15-05 Underreporting of complications	ETH.MESH.5560961	ETH.MESH.5560963
11/21/2005	Emails re !!!!GREAT NEWS FOR TVT LASER CUT MESH!!!! - Frayed mesh/particle loss	ETH.MESH.301741	ETH.MESH.301742
11/24/2005	Team conference call notes	ETH.MESH.00208897	ETH.MESH.00208897
11/25/2005	Silimkhan presentation Evaluation of Gynecare Prolene Meshes	ETH.MESH.00586019	ETH.MESH.00586019
12/2/2005	CER - Gynecare TVT Secur System	ETH.MESH.04385229	ETH.MESH.04385245
12/2/2005	Clinical Expert Report Gynecare TVT SECUR System	ETH.MESH.03714002	ETH.MESH.03714018
12/10/2005	Product Design Validation Report - Gynecare TVT Secur S	ETH.MESH.05530449	ETH.MESH.05530478
12/13/2005	St. Hilaire email chain re Clinical Expert Report Laser Cut Mesh	ETH.MESH.00998292	ETH.MESH.00998293
12/14/2005	Email from David Robinson (Medical Director) re Risk/Benefit Analysis for TVT SECUR Clinical Expert Report	ETH.MESH.823660	
12/19/2005	Mahar K mail chain re Lazer cut mesh	ETH.MESH.00687819	ETH.MESH.00687822
12/19/2005	Emails from Kevin Mahar re FW: Lazer cut mesh (Ex. T-3164)	ETH.MESH.687819	
12/20/2005	Presentation: SUI, A Primary Care Perspective	ETH.MESH.995657	
12/20/2005	Emails re: TVT Secur design validation study	ETH.MESH.06860393	ETH.MESH.06860398
12/21/2005	Honjnoski P email chain re CER - LCM	ETH.MESH.00700344	ETH.MESH.00700345
12/21/2005	Email re: Minutes of meeting: TVT SECUR design validation discussion 20th Dec 2005.	ETH.MESH.06860404	ETH.MESH.06860405
1/3/2006	Email from Mark Yale to Gary Borkes, Patricia Hojnoski, et al	ETH.MESH.06860410	
1/15/2006	Miller email chain re GYNECARE TVT Latest Complication Data	ETH.MESH.00134498	ETH.MESH.00134499
1/15/2006	Email Dennis Miller to Dharini Amin et al. re Gynecare TVT Latest Complication Data	ETH.MESH.00756887	ETH.MESH.00756888

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1/15/2006	Emails between Dharini Amin (Product Director Continence Health) and Dr. Dennis Miller re GYNECARE TVT Latest Complication Data - underreporting of complications	ETH.MESH.134498	ETH.MESH.134499
1/19/2006	Van Dijk email chain re Ti-mesh research	ETH.MESH.03908029	ETH.MESH.03908031
1/20/2006	London Brown email chain re TVT U Completion Report Version 3	ETH.MESH.01218594	ETH.MESH.01218596
1/26/2006	Vandenburgh 2005 Performance and Development Plan Summary for Christopher O'Hara	ETHMESH.OHARA.00000315	ETHMESH.OHARA.00000321
1/31/2006	Arnaud A email chain re TVT - TVT-O Specifications	ETH.MESH.03911712	ETH.MESH.03911715
2/1/2006	Global Regulatory Strategy GYNECARE TVT - Laser Cutting Project	ETH.MESH.00394544	ETH.MESH.00394553
2/6/2006	Robinson email chain re TVT complications	ETH.MESH.00847536	ETH.MESH.00847536
2/9/2006	Email re: TVT S DESIGN REVIEW (Design Validation)	ETH.MESH.00326236	ETH.MESH.00326238
2/9/2006	Email re: TVT S DESIGN REVIEW (Design Validation)	ETH.MESH.00326211	ETH.MESH.00326213
2/10/2006	Emailre:MajorRequestforHelptogetRE:DesignReviewTVT SECUR(DRMandDesignValidationPackaging)	ETH.MESH.00322464	ETH.MESH.00322466
2/13/2006	Email re: TVTS DESIGN REVIEWS	ETH.MESH.02324907	ETH.MESH.02324910
2/15/2006	Flatow J email chain re DVer protocol for particle loss	ETH.MESH.00584291	ETH.MESH.00584292
2/20/2006	Arnaud email chain re TVM discussions	ETH.MESH.03929173	ETH.MESH.03929177
2/23/2006	Memo Dan Lamont re TVT-Base & TVT-O Complaint Review for Laser Cut Mesh (LCM) Risk Analysis	ETH.MESH.00302390	ETH.MESH.00302392
2/23/2006	Email Cindy Crosby to Mark Yale, et al. re MHRA request - TVT blue pigment risk assessment	ETH.MESH.00330760	ETH.MESH.00330764
2/23/2006	TVT-Base & TVT-) Review for Laser Cut (LCM) Risk Analysis	ETH.MESH.302390	ETH.MESH.30292
2/24/2006	Lamont D Memo re TVT Laser Cut Mesh Risk Analysis Summary	ETH.MESH.00302105	ETH.MESH.00302106
2/24/2006	Lamont D Memo re TVT Laser Cut Mesh (LCM) Risk Analysis Summary	ETH.MESH.10984358	ETH.MESH.10984359
2/27/2006	Bonet email re Prolift Anatomy Images	ETH.MESH.00782152	ETH.MESH.00782152
2/28/2006	Robinson email re tvf - training	ETH.MESH.00846523	ETH.MESH.00846523
3/1/2006	Mahar email chain re Urgent Request: Revised TVt Complication data 2-9-06	ETH.MESH.00134029	ETH.MESH.00134031
3/2/2006	Email Dr. James Hart to David Robinson re tvf o training	ETH.MESH.04122262	ETH.MESH.04122264
3/6/2006	Kammerer memo re Elongation Characteristics of Laser Cut PROLENE Mesh for TVT	ETH.MESH.01222075	ETH.MESH.01222079
3/6/2006	Kammerer G Memo to Weisbert and Robinson re Elongation Characteristics of Laser Cut PROLENE Mesh for TVR	ETH.MESH.03358398	ETH.MESH.03358402
3/7/2006	Weisberg, Robinson Clinical Expert Report	ETH.MESH.01221735	ETH.MESH.01221740
3/7/2006	Weisberg, Robinson Clinical Expert report	ETH.MESH.01784823	ETH.MESH.01784828
3/9/2006	Kammerer G email chain re Elongation properties of LCM	ETH.MESH.01221618	ETH.MESH.01221619

DOCUMENTS

3/10/2006	Next Generation Mesh Discussion Agenda	ETH.MESH.00585672	ETH.MESH.00585673
3/10/2006	Urology University March 10-11, 2006	ETH.MESH.11920108	ETH.MESH.11920110
3/13/2006	Holste J email chair re Mesh and Tissue Contraction in Animal	ETH.MESH.05446127	ETH.MESH.05446128
3/20/2006	Flatow Completion Report for Design Verification of TVT Laser Cut Mesh	ETH.MESH.01219984	ETH.MESH.01219994
3/22/2006	TVT Slim Jim (TVT107)	ETH.MESH.00169748	ETH.MESH.00169751
3/29/2006	Email Daniel Lamont to Jacqueline Flatow re TVT LCM - design inputs	ETH.MESH.00302181	ETH.MESH.00302184
3/30/2006	Gadot email chain re Laser Cut Mesh Positioning (Redacted)	ETH.MESH.00700348	ETH.MESH.00700350
3/30/2006	Email Mark Yale re TVT laser cut equivalency	ETH.MESH.01945854	ETH.MESH.01945854
4/2/2006	Mahar K email chain re Laser Cut Mesh Positioning	ETH.MESH.06040171	ETH.MESH.06040173
4/7/2006	TVT IFU through	ETH.MESH.05222673	ETH.MESH.05222705
4/10/2006	An evaluation of the Gynecare TVT Tension-free support for incontinence and Gynecare TVT Obturator system tension-free support for incontinence with laser cut mesh - Amendment 1	ETH.MESH.10302268	ETH.MESH.10302279
4/17/2006	Kammerer G Memo re Justification for Utilizing the Elasticity Test as the Elongation Requirements on TVT Laser Cut Mesh	ETH.MESH.14450438	ETH.MESH.14450442
4/18/2006	CER Weisberg - Laser Cut Mesh	ETH.MESH.00167104	ETH.MESH.00167110
4/18/2006	Weisberg M and Robinson D CER	ETH.MESH.00998349	ETH.MESH.00998355
4/22/2006	TVT: Insights into Making of a Revolution by Sheri Dodd, VP, Worldwide, Health Economics and Reimbursement	ETH.MESH.6859904	
4/25/2006	Minute - Tactile appraisal of TVT LCM & LCM-MC both vs MCM	ETH.MESH.06696589	ETH.MESH.06696592
4/26/2006	Damotte M email chain re RE: Laser cut TVT - Surgeon's Preference Evaluation	ETH.MESH.10302266	ETH.MESH.10302267
5/1/2006	Kammerer G email chain re French Standard on TVT & Meshes (Comments required)	ETH.MESH.03358217	ETH.MESH.03358224
5/4/2006	Kammerer G email re New Standards for Urethral Slings	ETH.MESH.01221024	ETH.MESH.01221025
5/9/2006	Kammerer G email re Particle loss of TVT	ETH.MESH.00585802	ETH.MESH.00585802
5/9/2006	Flatow J email chair re Particle loss on TVT	ETH.MESH.01219629	ETH.MESH.01219630
5/9/2006	Mesh development timeline	ETH.MESH.01816990	ETH.MESH.01816990
5/9/2006	Email from Gene Kammerer (Engineering Fellow, R&D) re Particle Loss on TVT	ETH.MESH.585802	
5/18/2006	Class III License Amendment Application	ETH.MESH.10630324	ETH.MESH.10630449
5/22/2006	Sungyoon Rha email re First Human Use - Surgeon preference Questionnaire	ETH.MESH.00584175	ETH.MESH.00584178
5/22/2006	"World Premiere" as Ethicon Women's Health & Urology with special guest Bonnie Blair	HMESH_ETH_0184015 1	HMESH_ETH_0184015 2

DOCUMENTS

5/31/2006	Visual Acceptance Criteria for Blister Sealing; VSE0007, Revision: D	ETH.MESH.04321670	ETH.MESH.04321681
6/2/2006	Expert Meeting Minutes - Meshes for Pelvic Floor Repair	ETH.MESH.00870466	ETH.MESH.00870476
6/12/2006	Kammerer G email chain re TVT LCM - particle loss (reimbursement submission)	ETH.MESH.00585842	ETH.MESH.00585843
6/14/2006	Email Marie-Ange Damotte to Sungyoon Rha, et al. re TVT Laser Cut First Human Use - surgeon preference questionnaire	ETH.MESH.03274663	ETH.MESH.03274670
6/15/2006	Company Procedure for US Regulatory Affairs Review of Promotion and Advertising Materials for Medical Devices	ETH.MESH.08164248	ETH.MESH.08164256
6/22/2006	Gadot, Harel email re LCM - Launch Strategy EMEA	ETH.MESH.00998347	ETH.MESH.00998347
6/23/2006	St. Hilaire P email chain re LCM - Launch Strategy EMEA	ETH.MESH.00526484	ETH.MESH.00526487
6/26/2006	Product Pointer: Gynecare TVT Tension-free Support for Incontinence -- available in laser cut mesh	ETH.MESH.00167119	ETH.MESH.00167119
6/27/2006	Kammerer email chain re Urgent *** French Standard on TVT & Meshes (Comments Required)	ETH.MESH.00585823	ETH.MESH.00585832
6/29/2006	Meier email re Minutes Hamburg Meeting June 2nd	ETH.MESH.00870465	ETH.MESH.00870476
7/12/2006	GYNECARE Copy Review Submission - GYNECARE TVT SEC	ETH.MESH.05960712	ETH.MESH.05960713
7/14/2006	Trzewik email re Netzdiskussion	ETH.MESH.09671612	ETH.MESH.09671612
7/17/2006	TVT 20060717 Patient Brochure - Find out how to stop urine leakage like Bonnie did	ETH.MESH.08003215	ETH.MESH.08003230
7/20/2006	Email Paula Evans to David Robinson et al. re TVT dataMcNelis, Linda	ETH.MESH.00311802	ETH.MESH.00311804
8/1/2006	Jürgen email re Fotos cadeavar lab	ETH.MESH.05454207	ETH.MESH.05454207
8/13/2006	London Brown, A email chainre LIGHTning clinical strategy	ETH.MESH.00870481	ETH.MESH.00870482
8/28/2006	ICM Project Presentation	ETH.MESH.06001408	ETH.MESH.06001408
8/29/2006	Second half photo presentation. ppt	ETH.MESH.00584527	ETH.MESH.00584527
9/27/2006	TVT016R6 Patient brochure - Find out how to stop urine leakage like Bonnie did	ETH.MESH.08003231	ETH.MESH.08003246
10/4/2006	Mahar email chain re TVT LCM Early EU Feedback	ETH.MESH.00708571	ETH.MESH.00708576
10/4/2006	Hernandez J email chain re TVT LCM Early EU Feedback	ETH.MESH.00746204	ETH.MESH.00746208
10/9/2006	Email Cheryl Bogardus to Dharini Amin re TVT 10 year anniversary/10 year data from Nillson	ETH.MESH.00524059	ETH.MESH.00524060
10/18/2006	Smith, Dan email chain re TVT Secur - TVT-Classic roping/sheath issues - failure to warn	ETH.MESH.1822361	ETH.MESH.1822636
10/31/2006	Procedural Pearls & Frequently Asked Questions	ETH.MESH.03752501	ETH.MESH.03752506
11/6/2006	Email re: TVT-S Complaint review	ETH.MESH.00329316	ETH.MESH.00329317
12/18/2006	Patient advertisement for TVT	ETH.MESH.3460640	
12/19/2006	Smith, D email chain originating 12/15/2006 re TVT-S Cookbooks	ETH.MESH.519476	ETH.MESH.519481

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12/19/2006	Email re: TVT-S Cookbooks	ETH.MESH.01000726	ETH.MESH.01000730
12/19/2006	Email re: TVT-S Cookbooks	ETH.MESH.00519476	ETH.MESH.00519481
12/20/2006	Robinson, D, email chain originating 12/15/2006 re TVT-S Cookbooks	ETH.MESH.1784428	ETH.MESH.1784435
12/22/2006	Emails re Contact at Lifescan who ran the BB King Campaign	ETH.MESH.8345895	
1/2/2007	TVT sales piece (TVTS004)	ETH.MESH.00161512	ETH.MESH.00161513
1/16/2007	"Confidential: History of TVT-O" by Axel Arnaud	ETH.MESH.3932909	ETH.MESH.3932911
1/22/2007	Email re: Complaints TVT Secur - Germany	ETH.MESH.00324086	ETH.MESH.00324088
1/23/2007	Qually 2006 Performance and Development Plan Summary for O'Hara	ETHMESH.OHARA.00000322	ETHMESH.OHARA.00000327
1/23/2007	Email re: Portugal and your input regarding the surgical visits	ETH.MESH.02320485	ETH.MESH.02320489
1/25/2007	2005 Sales Rep Compensation Plan	ETH.MESH.5768705	ETH.MESH.5768712
2/6/2007	Mahar email chain re hospital concern from medico-legal standpoint	ETH.MESH.00719198	ETH.MESH.00719209
2/6/2007	St. Hilaire email chain re OBGYN Department Members. Due to the potential serious implications . . .	ETH.MESH.00722339	ETH.MESH.00722349
2/7/2007	Robinson email chain re PLEASE DO NOT DISTRIBUTE THIE EMAIL!!! . . .broadcase bulletin re Dr. Levy	ETH.MESH.02316434	ETH.MESH.02316436
2/9/2007	Presentation: The (clinical) argument of lightweight mesh in abdominal surgery by Boris Batke	ETH.MESH.05475773	ETH.MESH.05475822
2/13/2007	Email re: TVT-S	ETH.MESH.00330141	
2/20/2007	Lamont D email chain re Complaint Summaries	ETH.MESH.00303084	ETH.MESH.00303085
2/23/2007	Factors Related to Mesh Shrinkage: What do we know? A review of literature and internal studies	ETH.MESH.01782867	ETH.MESH.01782867
2/23/2007	Ethicon Expert Meeting: Meshes for Pelvic Floor Repair brochure	ETH.MESH.02017152	ETH.MESH.02017158
2/26/2007	Emails from David Robinson re modified version of TVT-O[TOT] procedure	ETH.MESH.00832937	ETH.MESH.00832939
3/14/2007	Email re: Conf call tomorrow	ETH.MESH.03922618	
3/20/2007	TVT-World-Wide Observational Registry for Long-Term Data Protocol 300-06-006 signed by David Robinson, Medical Director	ETH.MESH.539862	ETH.MESH.539898
3/22/2007	Email re: TVT World Registry Nilsson	ETH.MESH.07039973	ETH.MESH.07039975
4/5/2007	Spychaj K memo re Shrinking meshes	ETH.MESH.01218361	ETH.MESH.01218367
5/2/2007	Email re: TVT SECUR Recertification & Experts Meeting Paris 9-11 May	ETH.MESH.03922474	ETH.MESH.03922479
5/4/2007	Timmer message re updated Mesh Shrinkage Discussion meeting w/attachments	HMESH_ETH_06509815	HMESH_ETH_06509817
5/4/2007	Gynecare TVT Secur System: Key Technical Points (approved by Marketing on May 4, 2007)	ETH.MESH.00163952	ETH.MESH.00163960
5/11/2007	Email Price St. Hilaire to Dr Kavalier re AUA in Booth Activities	ETH.MESH.00136359	ETH.MESH.00136359

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5/15/2007	TVT Secur: European Feedback presentation by Axel Arna	ETH.MESH.00572598	
5/17/2007	Email re:TVT-Secur	ETH.MESH.03930698	ETH.MESH.03930708
5/18/2007	Email re: TVT Secure EU Experts meeting – feedback & fut	ETH.MESH.03922434	ETH.MESH.03922437
5/22/2007	Email re: TVT SECUR EU experts meeting – feedback & future actions	HMESH_ETH_01901877	HMESH_ETH_1901880
5/31/2007	Marketing Brochure - One day you have urine leakage. The next day you don't. End of Story.	ETH.MESH.08003263	ETH.MESH.08003278
6/1/2007	CDMA Eurpoe Meeting Urinary Incontinence Platform minutes June 1, 2007	ETH.MESH.03913651	ETH.MESH.03913665
6/1/2007	Trending analysis meeting presentation	ETH.MESH.14708810	ETH.MESH.14708848
6/5/2007	GYNECARE TVT SECUR Competitive Product Update 2007 by Dan Smith Dangerous Procedure/Tensioning	ETH.MESH.6861473	
7/6/2007	Engle email chain re How inert is polypropylene?	ETH.MESH.05447475	ETH.MESH.05447476
7/6/2007	Barbolt email chain re How inert is polypropylene	ETH.MESH.05447481	ETH.MESH.05447482
7/6/2007	Dr. Dieter Engle email chain re How inert is polypropylene?	ETH.MESH.5447475	
7/9/2007	Wohlert S email chain re How inert is polypropylene?	ETH.MESH.05588123	ETH.MESH.05588126
7/20/2007	Chomiak M email re Defining light weight mesh	ETH.MESH.05920616	ETH.MESH.05920617
7/20/2007	Emails between Paula Welland (UK Country Director), Paula Evans, and David Robinson re TVT data - underreporting of complications	ETH.MESH.311802	ETH.MESH.311804
7/20/2007	Emails re Defining light weight mesh	ETH.MESH.5920616	ETH.MESH.5920617
7/25/2007	Physician Brochure TVTS001RS - TVT SECUR System	ETH.MESH.00166287	ETH.MESH.00166292
7/26/2007	Email re: TVT SECUR Preceptor Meeting 8/24: Somerville, NJ	ETH.MESH.17666960	ETH.MESH.17666969
7/26/2007	Email re: TVT Secur Conference Call: Monday July 30th 4PM EDT	ETH.MESH.10213067	ETH.MESH.10213068
8/12/2007	Project plan Prosima M project lightning	ETH.MESH.03294572	ETH.MESH.03294581
8/19/2007	Incontinence Platform WW Marketing Team Update - Power Point	ETH.MESH.02105223	
8/22/2007	Ethicon Women's Health & Urology Submission Form	ETH.MESH.00166827	ETH.MESH.00166828
8/28/2007	Email from J. Sepulveda - Summary of the Critical Steps se	ETH.MESH.10226089	ETH.MESH.10226091
8/31/2007	Robinson D email Chain re Asking TVT Complication? - Fraying	ETH.MESH.00844341	ETH.MESH.00844344
9/5/2007	Email re: Secur agenda, etc	ETH.MESH.00844381	ETH.MESH.00844384
9/11/2007	Email re: case	ETH.MESH.00844439	
9/24/2007	EPC131 Revision A Neuchatel Prolift+M Product Specification	ETH.MESH.06214296	ETH.MESH.06214300
9/27/2007	Osman email chain re Wal-Mart Female Pelvic Health Poster Options	ETH.MESH.02114101	ETH.MESH.02114103
10/5/2007	Global Harms List Document for Review & Comment by Medical Affairs Personnel	ETH.MESH.06372356	ETH.MESH.06372363
10/12/2007	Email Dr. Meng Chen to Carolyn Brennan	ETH.MESH.4090122	
10/15/2007	Email re: TVT Secur Lessons Learned Review	ETH.MESH.00858636	ETH.MESH.00858641

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10/29/2007	Email re: TVT 0 versus TVT Secur efficacy and safety rates	ETH.MESH.00642325	ETH.MESH.00642331
10/30/2007	Email re: SECUR Update presented in at WW Mktg Meeting	ETH.MESH.03845446	ETH.MESH.03845449
10/31/2007	Gynecare TVT Secur system – Australian Postmarket Survey	ETH.MESH.00823421	ETH.MESH.00823422
11/1/2007	11.1.07 Internal Australian Meeting Re Secur	ETH.MESH.04126728	ETH.MESH.04126730
11/1/2007	Gynecare TVT Secur System – Postmarket Surveillance Review Meeting	ETH.MESH.04126728	ETH.MESH.04126730
11/2/2007	Beath email chain re Meeting with the Australian Regulator to discuss TVT Secur performance	ETH.MESH.00312179	ETH.MESH.00312182
11/2/2007	Email RE: Meeting with the Australian Regulator to discuss TVT-S performance	ETH.MESH.00312179	ETH.MESH.00312182
11/2/2007	Email re: Gynecare TVT SECUR Technical Guide & Updates	ETH.MESH.00832190	ETH.MESH.00832201
11/3/2007	Robinson email chain re URGENT: Meeting with the Australian Regulator to discuss TVT Secur performance	ETH.MESH.00326865	ETH.MESH.00326870
11/5/2007	Email re: URGENT: Meeting with the Australian Regulator	ETH.MESH.00326842	ETH.MESH.00326846
11/12/2007	Aran Maree Email chain originating 11/08/2007 re Australia update and telephone call with Prof Frazer - "the IFU is fundamentally misleading . . ."	ETH.MESH.311792	ETH.MESH.311794
11/26/2007	Email re: TVT-S update	ETH.MESH.00874526	ETH.MESH.00874528
11/30/2007	Email re: TVT SECUR Breakout	ETH.MESH.10212343	ETH.MESH.10212346
12/10/2007	Email re: TGA update for TVT Secur	ETH.MESH.04127069	ETH.MESH.04127071
1/2/2008	Email re: SECUR Markets: TVT SECUR - Critical Steps Guide	ETH.MESH.06051377	ETH.MESH.06051381
1/8/2008	Flores email chain re New complaint acknowledgement/request for info 10100062684	ETH.MESH.03509909	ETH.MESH.03509910
1/9/2008	Maree, A email chain re TGA Meeting	ETH.MESH.04127133	ETH.MESH.04127134
2/4/2008	Ullmann 2007 Performance and Development Plan Summary for O'Hara	ETHMESH.OHARA.00000328	ETHMESH.OHARA.00000333
2/5/2008	ETHICON, INC. Worldwide Complaint - Reporting Statement	ETH.MESH.00148908	
2/7/2008	Kahlson H email chain re Conversion to Laser Cut TVT	ETH.MESH.16416002	ETH.MESH.16416004
2/7/2008	Email re: Conversion to Laser Cut TVT.	ETH.MESH.16416002	ETH.MESH.16416004
2/8/2008	Master Consulting Agreement between Ethicon (signed by Price St. Hilaire) and Carl Nilsson	ETH.MESH.08692660	ETH.MESH.08692667
2/8/2008	Nilsson Master Consulting Agreement	ETH.MESH.08692936	ETH.MESH.08692943
2/19/2008	Pelvic Floor Summit	ETH.MESH.00057336	ETH.MESH.00057374
2/19/2008	Final Report Evaluation of Area Weight, PP Amount, Tensile Strength	ETH.MESH.10616895	ETH.MESH.10616956
2/21/2008	Vie email chain re TVTO vs. Boston Obtryx	ETH.MESH.07937979	ETH.MESH.07937981
2/22/2008	Executive Summary - Preliminary results of peri-operative and 3-month outcomes from a world-wide observational registry of tension-free vaginal tapes in with with SUI	ETH.MESH.01775242	ETH.MESH.01775257

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2/29/2008	MiniMe R & O Final	ETH.MESH.858891	
3/3/2008	Robinson D email chain re Quality issue with a batch of gynemesh	ETH.MESH.00328895	ETH.MESH.00328901
3/3/2008	Harel Gadot email with attached diagram	ETH.MESH.1279975	
3/3/2008	David Robinson email chain re Quality issue with a batch of gynemesh	ETH.MESH.328895	
3/4/2008	Gadot H email chain re Next step in SUI Sling	ETH.MESH.02293673	ETH.MESH.02293677
3/5/2008	Lamont D email chain re Gynemesh issue	ETH.MESH.00303944	ETH.MESH.00303945
3/14/2008	Risk Management Report (Legacy) for TVT and TVT-O	ETH.MESH.1265223	ETH.MESH.1265239
3/19/2008	Email Kyung Yu to Susie Chilcoat re Flynn preceptorships	ETH.MESH.03614158	ETH.MESH.03614158
3/19/2008	TVT 20080319 Gynecare TVT Family of Products Patients Brochure/Robin Osman	ETH.MESH.3458123	ETH.MESH.3458138
3/24/2008	Mahar K email chain re Project SCION Update & Next Steps	HMESH_ETH_0188106 0	HMESH_ETH_0188106 2
3/25/2008	CommunicationtoSurgeonsRegardingtheGynecareTVTSe curSystem(signedbyDr.AranMaree–Medical Director – Australia and New Zealand)	ETH.MESH.00326804	
3/26/2008	Bonnie Blair - Find out how to stop uring leakage like Bonnie did	ETH.MESH.03458123	ETH.MESH.03458138
4/12/2008	Gauld email chain re Follow-up on US visit	ETH.MESH.03162936	ETH.MESH.03162938
4/15/2008	Trip Notes	ETH.MESH.02090196	ETH.MESH.02090209
4/15/2008	04/15/2008 Notes	ETH.MESH.03916716	ETH.MESH.03916727
4/15/2008	04/15/2008 Trip Notes	ETH.MESH.09909642	ETH.MESH.09909655
4/15/2008	Notes	ETH.MESH.3916716	
4/15/2008	Notes based on CHU cadaver session	ETH.MESH.03916716	ETH.MESH.03916727
4/16/2008	04/16/08 Notes	ETH.MESH.10003595	ETH.MESH.10003603
4/23/2008	Hernandez J email chain re Liege Trip Notes	ETH.MESH.03916715	ETH.MESH.03916715
4/29/2008	Lamont D email chain re Post Launch Reviews	ETH.MESH.00304013	ETH.MESH.00304014
5/1/2008	Update to the TGA on TVT Secur	ETH.MESH.05404976	
5/2/2008	Arnaud email re Mini TVT-O timeline	ETH.MESH.03914631	ETH.MESH.03914631
5/5/2008	Arnaud email chain re sling business for SUI	ETH.MESH.03914629	ETH.MESH.03914630
5/6/2008	Form letter re TVTS4-Gynecare TVT Secur System	ETH.MESH.12939705	ETH.MESH.12939705
5/16/2008	Email Krystina Laguna to Price St. Hilaire re Copy Review TVT Complications	ETH.MESH.00345289	ETH.MESH.00345291
6/4/2008	Linton email re AUGS attendees	ETH.MESH.00057335	ETH.MESH.00057335
6/6/2008	Nilsson, et al. "Eleven years prospective follow-up of the tension-free vaginal tape procedure for treatment of stress urinary incontinence"	ETH.MESH.00355003	ETH.MESH.00355007
6/18/2008	KOL Interview: Carl G. Nilsson regarding Next Generation Mini-Sling	ETH.MESH.04048515	ETH.MESH.04048520
6/30/2008	Lepley email chain re Urgent New complaint/request for information	ETH.MESH.03502981	ETH.MESH.0350298Y

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7/29/2008	Kadackia R email chain re TVT LCM - launch delay due to OQ failure	ETH.MESH.09004550	ETH.MESH.09004553
8/14/2008	TVT Brochure "The Choice to End Stress Urinary Incontinence. Find out how to stop urine leakage like Bonnie did"	ETH.MESH.03459088	ETH.MESH.03459104
8/27/2008	Brennan email chain re TVT-S Mesh Torn Complaint Review for Wednesday morning Conf Call	ETH.MESH.09504558	ETH.MESH.09504559
8/27/2008	Scavona email chain re PQI TVT S	ETH.MESH.09504568	ETH.MESH.09504571
9/5/2008	FOR IMMEDIATE RELEASE: New Study Offers More Than a Decade of Evidence for Minimally-Invasive Surgery to Treat Female Incontinence	ETH.MESH.03459211	ETH.MESH.03459212
9/24/2008	Email Melissa Day to Meng Chen, et al. re #10100078150	ETH.MESH.04099233	ETH.MESH.04099234
9/24/2008	Email Marcus Oldelehr to Brian Flynn re Flynn visit 10/23	ETH.MESH.19354118	ETH.MESH.19354119
9/25/2008	TVT sales piece	ETH.MESH.00164643	ETH.MESH.00164648
9/25/2008	Arnaud A email re TVT World registry	ETH.MESH.03914909	ETH.MESH.03914909
9/28/2008	Email re: TVT Secur- re-training	ETH.MESH.04127331	
10/8/2008	Chaves email re MiniSling Abstract Overview & Nilsson Podcast	ETH.MESH.02123291	ETH.MESH.02123291
10/13/2008	Email from Jennifer Paine (WW Director, Regulatory Affairs) re FDA Public Health Notice on Surgical Mesh for POP and SUI - URGENT Product Defect Failure to Disclose Adverse Risks/Complications	ETH.MESH.329112	ETH.MESH.329113
10/14/2008	Voicemail from Kevin Mahar to EWH&U Sales & Marketing Organization re FDA PHN Product defect	ETH.MESH.66960	
10/20/2008	FDA Public Health Notification: Serious Complications Associated with Transvaginal Placement of Surgical Mesh in Repair of POP and SUI	ETH.MESH.7937826	ETH.MESH.7937828
10/21/2008	FINAL FDA Notification About Use of Surgical Mesh to Treat POP and SUI Standby for Media/Analyst Inquiries	ETH.MESH.164023	ETH.MESH.164027
10/21/2008	Email from Renee Selman (WW President, Ethicon WH&U) to EWHU Team re Information about FDA notification on use of mesh in pelvic surgery	ETH.MESH.2310653	ETH.MESH.2310657
11/1/2008	Piete Hinoul, MD Presentation: The future of surgical meshes: the industry's perspective	ETH.MESH.1203957	
11/13/2008	Smith D memo: Things to consider as we assess next steps for a next generation sling	ETH.MESH.09911296	ETH.MESH.09911299
12/9/2008	Presentation: "Stop Coping. Start Living. Treatment Options for Urinary Incontinence."	ETH.MESH.01673341	ETH.MESH.01673341

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12/10/2008	TVT 20081210 TVT - Treatment Options for Stress Urinary Incontinence	ETH.MESH.8003279	ETH.MESH.8003294
12/11/2008	Linda Linton email chain re TVT 11 Year E-blast Results (1st Round)	ETH.MESH.5183409	ETH.MESH.5183410
12/17/2008	Osman email chain . . . Unfortunately we can't print the new brochure . . . Regulatory rejected my Copy Review submission . . .	ETH.MESH.772228	ETH.MESH.772229
12/18/2008	Universite De Liege and Ethicon Licensing Agreement	ETH.MESH.12002262	ETH.MESH.12002280
12/18/2008	Lisa email chain re TVT Patient Brochure Fair Balances/EPI Changes Change risks to brochure	ETH.MESH.339083	ETH.MESH.339084
12/19/2008	Email from Meng Chen to Sergio Gadaleta and Mark yale re #10100080654 and TVT IFUs	ETH.MESH.4092868	
1/1/2009	2009 Performance and Development Plan Summary for Christopher O'Hara	ETHMESH.OHARA.00000340	ETHMESH.OHARA.00000346
1/7/2009	Kirkemo A email chain re My revised writeup of the DeLeval and Waltregny Visit	ETH.MESH.01202101	ETH.MESH.01202103
1/7/2009	Hinoult P email chain re My revised writeup of the DeLeval and Waltregny visit	ETH.MESH.03916905	ETH.MESH.03916913
1/7/2009	Total Petrochemicals Certificate N° 9	ETH.MESH.09955474	ETH.MESH.09955479
1/23/2009	Hinoult memo re meeting with Prof DeLeval and Prof Waltregny	ETH.MESH.04050265	ETH.MESH.04050265
1/25/2009	Letter re: Deleval	ETH.MESH.4050265	
1/26/2009	Issue Report	ETH.MESH.11985160	ETH.MESH.11985164
1/26/2009	Email from Joseph Scavona (Worldwide Quality) re TVT Complications Statement 2008 with attached draft slide of Complaint Reporting Statement with most significant reported TVT complications through December 2008	ETH.MESH.2122903	ETH.MESH.2122907
1/28/2009	Hinoult P email chain re TVT World AE Report	ETH.MESH.03208548	ETH.MESH.03208549
1/28/2009	Urquhart email re TVT World AE Report w/attachment	ETH.MESH.07181044	ETH.MESH.07181044
1/29/2009	Chen M email re TVT IFUs on tape extrusion, exposure and erosion	ETH.MESH.04093125	ETH.MESH.04093125
1/29/2009	Emails Bryan List to Meng Chen et al. re TVT IFUs on tape extrusion, exposure and erosion	ETH.MESH.04094863	ETH.MESH.04094864
1/29/2009	Email re: TVT IFUs on tape extrusion, exposure and erosion	ETH.MESH.04093117	ETH.MESH.04093118
2/2/2009	Meeting Agenda "AE and complication of the Isings	ETH.MESH.04081189	ETH.MESH.04081190
2/6/2009	Haby email re CR Approved 2009-98	ETH.MESH.00007091	ETH.MESH.00007091
2/23/2009	Zipfel R email chain re Ultrapro mesh info	ETH.MESH.07383730	ETH.MESH.07383731
2/25/2009	Email Jason Hernandez re Quick Response Needed to Finalize TVT WORLD Recommendation for Board Meeting on Monday Mar 2nd	ETH.MESH.03208738	ETH.MESH.03208738
2/27/2009	Ciarrocca S email FW MiniMe discussion at the gboard meeting	ETH.MESH.09951746	ETH.MESH.09951793

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2/27/2009	Email re: TVT WORLD Board meeting presentation	ETH.MESH.00134794	ETH.MESH.00134795
3/2/2009	Hernandez J email chain re EWHU Board recommendation	ETH.MESH.00827376	ETH.MESH.00827379
3/4/2009	- Mini TVT-O Technical Assessment	ETH.MESH.06928076	ETH.MESH.06928077
3/5/2009	Interim report mesh explants pelvic floor repair	ETH.MESH.6636	
3/6/2009	Emails Scott Finley to Melissa Chaves re Fast Break Update	ETH.MESH.03966039	ETH.MESH.03966040
3/6/2009	Ciarrocca email re Sling thoughts and next steps 11-13-08.doc	ETH.MESH.09951087	ETH.MESH.09951090
3/9/2009	Ullmann 2008 Performance and Developmnet Plan Summary for Christopher O'Hara	ETHMESH.OHARA.00000334	ETHMESH.OHARA.00000339
3/11/2009	Physican brochure/sales aid "Make Data and Safety your Choice"	ETH.MESH.00339053	ETH.MESH.00339057
3/11/2009	Hinoul P email re EJOGB-08-4159R1 - Minor Revision	ETH.MESH.00590896	ETH.MESH.00590897
3/17/2009	Ciarrocca S email re Updated Mini TVT-O Deck	ETH.MESH.01147115	ETH.MESH.01147115
3/19/2009	Mini TVT-O Stage Gate: SBT Discovery Initiation	ETH.MESH.01147116	ETH.MESH.01147116
3/19/2009	Mahar email chain re Credo debrief	ETH.MESH.06040657	ETH.MESH.06040658
3/20/2009	Letter Patricia Beach (Ethicon) to Dr. Douglas Grier re TVT World Registry	ETH.MESH.00407285	ETH.MESH.00407285
3/23/2009	Hinoul Protocol proposition - Modified TVT-O for the treatment of female stress incontinence: anatomical considerations	HMESH_ETH_02571221	HMESH_ETH_02571226
3/28/2009	Aaron Kirkemo email re My revised writeup of the DeLaval and Waltregny visit	ETH.MESH.1202101	
3/31/2009	Hinoul email re Mini TVTO	ETH.MESH.09952163	ETH.MESH.09952167
3/31/2009	Email Katrin Elbert to Piet Hinoul RE: MiniTVTO	ETH.MESH.09952168	ETH.MESH.09952169
4/1/2009	Lisa B email re TVT-Mini clinical support	ETH.MESH.00346227	ETH.MESH.00346227
4/8/2009	Hinoul email chain re registry for all!	ETH.MESH.00591127	ETH.MESH.00591128
4/8/2009	Hinoul email chain re Tensile Properties of POP Mesh	ETH.MESH.05238373	ETH.MESH.05238374
4/9/2009	Jones, S email re Tensile Properties of POP Mesh	ETH.MESH.05238382	ETH.MESH.05238384
4/20/2009	Chaves M email chain re CR Approved 2009-471 What's Left Behind Abbrevio	ETH.MESH.00057513	ETH.MESH.00057514
4/20/2009	Piet Hinoul letter re meeting with Prof deLeval and Prof Waltregny	ETH.MESH.01238552	ETH.MESH.01238553
4/22/2009	Email Piet Hinoul to Dan Smith re Meeting Minutes Prof deLeval 20/04/09	ETH.MESH.01238538	ETH.MESH.01238541
4/22/2009	Email Piet Hinoul to Katrin Elbert et al. re Meeting Minutes Prof deLeval 20/04/09	ETH.MESH.01238551	ETH.MESH.01238551
4/23/2009	Mini TVT-O Team Meeting	ETH.MESH.03643186	ETH.MESH.03643187
4/23/2009	Mini TVT-O Team Meeting	ETH.MESH.09956613	ETH.MESH.09956614
4/24/2009	Email Judi Gauld to Colin Urquhart re green journal	ETH.MESH.03259439	ETH.MESH.03259440
4/24/2009	Email Katrin Elbert to Anna-Caroline Cornec re Mesh strip for Mini-TVT O	ETH.MESH.09955374	ETH.MESH.09955374
4/24/2009	Elbert K email re Mesh strip for Mini-TVTO	ETH.MESH.17556513	ETH.MESH.17556513

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4/28/2009	TVT-World-Wide Observational Registry for Long-Term Data	ETH.MESH.00533250	ETH.MESH.00533256
4/30/2009	Email Henri Decloux to Valerie Emperado re T-Con follow up	ETH.MESH.06928168	ETH.MESH.06928168
5/7/2009	Prolift+M Piet Hinoul, MD Pelvic Floor Meeting - Nederland, Utrecht, May 7, 2009	ETH.MESH.1264260	
5/15/2009	Email Katrin Elbert to Henri Decloux re Last week's Medi-Line visit	ETH.MESH.09957926	ETH.MESH.09957927
5/20/2009	Email Stale Kvitle to Jean DeLeval, et al. re Mini Me follow up from our visit	ETH.MESH.15285672	ETH.MESH.15285672
5/26/2009	Brennan email chain re TVT Complications Statement 2008	ETH.MESH.02122903	ETH.MESH.02122905
5/26/2009	All Active CAPA's	ETH.MESH.02250914	ETH.MESH.02250945
5/26/2009	ASTM Designation: F 2097 - 08 Standard Guide for Design and Evaluation of Primary Flexible Packaging for Medical Products	ETH.MESH.06806078	ETH.MESH.06806092
6/2/2009	Email re: TVT-S follow up	ETH.MESH.06070148	ETH.MESH.06070154
6/3/2009	Chaves email re Fast Break Promotion Update	ETH.MESH.04314739	ETH.MESH.04314740
6/4/2009	Email re: PAR techniek TVTS Sepulveda	ETH.MESH.02596701	ETH.MESH.02596704
6/8/2009	Gynecare TVT Family of Products Tension-free Support for Incontinence Creative Brief Template	ETH.MESH.01184277	ETH.MESH.01184277
6/11/2009	Divilio Memo re The Use of Mesh in Hernia Repair	ETH.MESH.14442958	ETH.MESH.14442976
6/15/2009	Subramanian D email chain re Mini TVTO HE1 assessment	ETH.MESH.09960437	ETH.MESH.09960439
6/19/2009	Sunoco MSDS 2009	ETH.MESH.10630809	ETH.MESH.10630813
6/26/2009	Email Brian Flynn to Jonathan Fernandez re Contracted Pricing	ETH.MESH.08007248	ETH.MESH.08007249
6/29/2009	Hurley M email chain re SBT Meeting	ETH.MESH.07402878	ETH.MESH.07402879
7/1/2009	AdvaMed Code of Ethics on Interactions with Healthcare Professionals	ETH.MESH.00139845	ETH.MESH.00139867
7/15/2009	Email Brian Langen to Vincenza Zaddem re Plus-M payment for Mel Anhalt	ETH.MESH.10133116	ETH.MESH.10133116
7/16/2009	Robinson D email chain re TVT RR IFU Version 5 071409_T-3466	ETH.MESH.01239065	ETH.MESH.01239066
7/21/2009	Subramanian D email chain re EGS Mini TVTO	ETH.MESH.02322544	ETH.MESH.02322546
7/28/2009	Bobertz email chain re URGENT: Resin information request	ETH.MESH.06239100	ETH.MESH.06239108
7/30/2009	Email Takahito Hino to Patrice Napoda re TVT Japanese Package Insert	ETH.MESH.03656697	ETH.MESH.03656699
8/1/2009	2009 Field Visit Letter	ETH.MESH.10233144	ETH.MESH.10233148
8/7/2009	Email Severine Timoner Fortin to Valerie Emperado et al. re For Information - lot of TVT used for DeLeval's tests	ETH.MESH.09951106	ETH.MESH.09951107
8/7/2009	Email Henri Decloux to Severine Timoner Fortin re Quote for sample production	ETH.MESH.09958050	ETH.MESH.09958051

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8/8/2009	Hinoult email chain re For Information - lot of TVT used for Deleval's tests	ETH.MESH.09954485	ETH.MESH.09954486
8/17/2009	Prine email chain re TVT promotion Slam Dunk Winners	ETH.MESH.10227358	ETH.MESH.10227359
8/21/2009	Email David Waltregny to Piet Hinoul re TR: For Information - lot of TVT used for Deleval's tests	ETH.MESH.02596464	ETH.MESH.02596467
8/27/2009	Timoner Fortin email re Mini-O Raw material proposed by Suppliers for button aid	ETH.MESH.09955464	ETH.MESH.09955464
9/11/2009	Mini TVT-O Stage Gate: Charter presentation	ETH.MESH.00758412	ETH.MESH.00758412
9/14/2009	Savidge S email chain re TVT RR IFU 090911b_T-3467	ETH.MESH.00592915	ETH.MESH.00592916
9/17/2009	Email Paul DeCosta to Thomas Divilio, et al. re: Mesh + Anti-proliferative agent	ETH.MESH.03722384	ETH.MESH.03722386
9/22/2009	Hinoult P email chain re TVTO mini IFU rewrite	ETH.MESH.00209295	ETH.MESH.00209299
9/25/2009	Savidge S email chain re TVTO Mini IFU questions	ETH.MESH.09952714	ETH.MESH.09952715
9/28/2009	Master Consulting Agreement between Brian J. Flynn and Ethicon	ETH.MESH.03618587	ETH.MESH.03618596
9/29/2009	Communication Plan to close TVT World Registry	ETH.MESH.00533283	ETH.MESH.00533286
10/7/2009	Email Sandy Savidge to Katrin Elbert re TVTO mini IFU rewrite	ETH.MESH.00209965	ETH.MESH.00209968
10/19/2009	Email re: TVT EXACT IFU Proof Read 9/14/09	ETH.MESH.00211259	ETH.MESH.00211260
10/21/2009	Email chain from Susan Lin re TVT EXACT IFU Proof Read 9/14/09	ETH.MESH.211263	
10/26/2009	Email from John Young to Aaron Kirkemo re IFU	ETH.MESH.10632650	
11/10/2009	Mini TVT-O Team Meeting	ETH.MESH.211038	ETH.MESH.211041
12/22/2009	Run on eg log.txt	ETH.MESH.3334244	
1/1/2010	Ethicon Women's Health and Urology Brand Equity Study	ETH.MESH.03643186	
1/4/2010	Monthly Closed CAPA	ETH.MESH.03832685	ETH.MESH.03832692
1/5/2010	Timoner Fortin, S email chain re Prosima learning's at preceptor sites EMEA	ETH.MESH.00077727	ETH.MESH.00077732
1/8/2010	Global Regulatory Strategy for TVT IFU (RMC P15506/E) Update (Part II, RA0001-2010, Rev. 0) by Susan Lin to John Young	ETH.MESH.00340990	ETH.MESH.00340999
1/17/2010	Hinoult, P email chain re +M relaxation	ETH.MESH.01785259	ETH.MESH.01785260
1/21/2010	TVT Marketing email re 2010 Planning -- "Voice of the Customer" feedback	ETH.MESH.09234953	ETH.MESH.09234954
1/27/2010	TVT ad "Demand the most proven technology when selecting a mid-urethral sling... Make DATA and SAFETY YOUR CHOICE"	ETH.MESH.00349508	ETH.MESH.00349512
1/28/2010	Flores email chain re Continence Health Brand Team - TVT Feedback	ETH.MESH.09234951	ETH.MESH.09234952
2/6/2010	Peebles R email re Mesh slides for NTM	ETH.MESH.01805963	ETH.MESH.01805963
2/8/2010	Kirkemo A email chain re TVT Abbrevio and surgicenters	ETH.MESH.08581412	ETH.MESH.08581413
2/12/2010	2010 TVTS-029-10-2/12	ETH.MESH.02237103	ETH.MESH.02237104

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2/16/2010	Toglia M email chain re Ethicon Women's Health and Urology National Training meeting - TVT	ETH.MESH.09235084	ETH.MESH.09235085
2/17/2010	Gynecare TVT Device Instructions for Use Revision Design Verification Memo by Kirkemo, Robinson and Hinoul	ETH.MESH.00340839	ETH.MESH.00340839
2/17/2010	Holste email chain re PP vs PVDF or Pronova	HMESH_ETH_00228961	HMESH_ETH_00228973
2/19/2010	Beath C email re clinical data	ETH.MESH.02254087	ETH.MESH.02254087
2/24/2010	Gauld J email chain re TVT-Abbrevio	ETH.MESH.00350720	ETH.MESH.00350720
2/24/2010	Email Jonathan Fernandez to Carol Padgett re Dr. Alvina Driscoll	ETH.MESH.08014324	ETH.MESH.08014327
2/25/2010	Robinson D email chain re TVT Abbrevio	ETH.MESH.00073089	ETH.MESH.00073093
2/25/2010	Pruden G email chain re Concerns raised re TVT Abbrevio surgical procedure	ETH.MESH.00207012	ETH.MESH.00207015
2/25/2010	Robinson D email chain re Concerns raised re TVT Abbrevio surgical procedure	ETH.MESH.03923426	ETH.MESH.03923430
2/25/2010	Magalhaes I email chain re Concerns raised re TVT Abbrevio surgical procedure	ETH.MESH.06378084	ETH.MESH.06378089
2/26/2010	Physician brochure/sales aid	ETH.MESH.00659430	ETH.MESH.00659431
2/27/2010	Peebles R email re Rogliam participation in presentation	ETH.MESH.09214438	ETH.MESH.09214438
3/2/2010	Elbert K email chain re first draft equivalence Abbrevio	ETH.MESH.09956434	ETH.MESH.09956437
3/4/2010	EWHU 2009 Awards Ceremony	ETH.MESH.16263696	ETH.MESH.16263715
3/10/2010	Savidge S and Johnson L - biocompatibility statement	ETH.MESH.00074068	ETH.MESH.00074070
3/10/2010	Kirkemo A email re Scion PA commercial recommendation	ETH.MESH.00607406	ETH.MESH.00607410
3/10/2010	Kirkemo A email chain re Scion PA commercial recommendations	ETH.MESH.06927231	ETH.MESH.06927235
3/16/2010	Savidge S email chain re First draft equivalence Abbrevio	ETH.MESH.00351697	ETH.MESH.00351701
3/17/2010	Hibon email re TVT-Standard production stopped due to metallic particle on needles	ETH.MESH.13906093	ETH.MESH.13906093
3/17/2010	Ullman email chain re "Take Back Share" - Feb Update	ETH.MESH.19306944	ETH.MESH.19306946
3/19/2010	Bryan L email chain re EBM Sub-team meetings for EWHU	ETH.MESH.01201387	ETH.MESH.01201389
3/19/2010	Smith D email re Information regarding Scion	ETH.MESH.06927248	ETH.MESH.06927249
3/23/2010	Smith D email chain re Input to the one-pager to BR	ETH.MESH.00351439	ETH.MESH.00351441
3/23/2010	Kirkemo A email re Meeting with Bridget O Transformation nature of Scion delivery system	ETH.MESH.00600985	ETH.MESH.00600987
3/23/2010	Smith email chain re information regarding Scion	ETH.MESH.01216820	ETH.MESH.01216822
3/23/2010	Dormier E email chain re Meeting with Bridget - Transformation nature of Scion delivery system	ETH.MESH.01216831	ETH.MESH.01216833
3/24/2010	Iacobone email chain re Stability Testing	ETH.MESH.09932848	ETH.MESH.09932849
3/25/2010	Draft TVT Family strategic positioning overview presentation	ETH.MESH.00212665	ETH.MESH.00212665

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3/25/2010	Gynecare TVT Abbrevio Launch Planning Stage Gate EWHU Board presentation	ETH.MESH.01538120	ETH.MESH.01538120
3/25/2010	Zaddem V email chain re Your input on 30 in 3 and Speed to launch	ETH.MESH.02013947	ETH.MESH.02013948
4/6/2010	Elbert K email chain re CO-0022344 for your review; Target Approval 4-12-2010 12:00:00 AM EDT	ETH.MESH.10632641	ETH.MESH.10632644
4/6/2010	Taggart D email chain re CO-002344 for your review: Target Approval 04-12-2010 12:00 AM EDT	ETH.MESH.14819286	ETH.MESH.14819290
4/7/2010	Robinson D email re Please hold: database study vendor selection	ETH.MESH.00602025	ETH.MESH.00602027
4/9/2010	NCR Summary Report NCR10-01914	ETH.MESH.05620358	ETH.MESH.05620362
4/12/2010	Extend the control of your hand 2010 TVTE-187-10-4/12 sales aid	ETH.MESH.02235661	ETH.MESH.02235664
4/14/2010	TVT Retropublic Refresh	ETH.MESH.00223801	ETH.MESH.00223828
4/15/2010	Project Mini TVT-O Team: Gynecare TVT Abbrevio Continence System	ETH.MESH.09922406	ETH.MESH.09922406
4/19/2010	Waltregny D email chain re Your Submission	ETH.MESH.00574783	ETH.MESH.00574783
4/19/2010	Wess A email chain re de leval paper	ETH.MESH.03627114	ETH.MESH.03627114
4/19/2010	Minutes for Project Mini TVTO Design Outputs Design Review	ETH.MESH.16433747	ETH.MESH.16433756
4/28/2010	TVT Family of Products Co-positioning EWHU Board Pre-Reading	ETH.MESH.00750880	ETH.MESH.00750881
5/12/2010	TVT-O IFU (05/12/2012-present)	ETH.MESH.02340902	ETH.MESH.02340973
5/14/2010	Kirkemo A email chain re Review of Scion 2 year data	ETH.MESH.01252509	ETH.MESH.01252512
5/14/2010	Biocompatibility Assessment of Medi-Line Use of Down Corning 200 Fluid (100 cst) In Gynecare TVT Products	ETH.MESH.01320395	ETH.MESH.01320519
5/14/2010	Barendse email re TVT Exact Meeting Follow-up	ETH.MESH.10232709	ETH.MESH.10232709
5/18/2010	TVT Abbrevio Launch Planning Stage Gate PLT brochure	ETH.MESH.03753682	ETH.MESH.03753682
5/18/2010	Gynecare TVT Abbrevio Launch Planning Stage Gate PLT	ETH.MESH.09183969	ETH.MESH.09184024
5/18/2010	TVT Abbrevio Launch Planning Stage Gate PLT	ETH.MESH.09294125	ETH.MESH.09294125
5/18/2010	Stagegate Presentation - slide 41 - projected COGS, AS...	ETH.MESH.09936426	ETH.MESH.09936427
5/28/2010	Consulting Agreement Requisition Form between Brian J. Flynn and Ethicon	ETH.MESH.00493332	ETH.MESH.00493343
6/11/2010	Jones email chain re Prosima Preceptorships	ETH.MESH.08023341	ETH.MESH.08023342
6/14/2010	2011 EWHU Business Planning presentation	ETH.MESH.03642659	ETH.MESH.03642659
6/16/2010	Hart email chain re Investigator-Initiated Studies Policy	ETH.MESH.05347751	ETH.MESH.05347769
6/16/2010	NCR Summary Report NCR10-02107	ETH.MESH.05620371	ETH.MESH.05620382
6/16/2010	NCR Summary Report NCR10-02199	ETH.MESH.05620383	ETH.MESH.05620388
6/29/2010	Lisa B email re TVT Abbrevio claims support	ETH.MESH.00346157	ETH.MESH.00346157
6/29/2010	Smith email re New TVT +M mesh	ETH.MESH.04987190	ETH.MESH.04987191

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6/30/2010	Landgrebe S email chain re matrix-Cohera	ETH.MESH.06869163	ETH.MESH.06869166
7/1/2010	TVT-Abbrevio FDA communication and 510k	ETH.MESH.00343129	ETH.MESH.00343225
7/1/2010	TVT Abbrevio 510(k) Clearance and Application	ETH.MESH.05224295	ETH.MESH.05224391
7/5/2010	MD&D Complaint Form - Complaint ID CC1007005	ETH.MESH.03497846	ETH.MESH.03497847
7/5/2010	Email Kathie Chen to Darlene Jane Kyle, et al. re Product Complaint CC1007005-Taiwan	ETH.MESH.13204508	ETH.MESH.13204521
7/6/2010	Beath C email chain re 510K clearance	ETH.MESH.02254165	ETH.MESH.02254165
7/7/2010	Peter K email re TOPA timing - draft for review and input	ETH.MESH.02178872	ETH.MESH.02178873
7/12/2010	Poulot email chain re BHR EWHU 3413118, 398077, 3405428	ETH.MESH.13896042	ETH.MESH.13896043
7/13/2010	Samuel S email re Key Steps Flashcare Clarification	ETH.MESH.01675805	ETH.MESH.01675806
7/15/2010	Email Vincenza Zaddem to Alyssa Kilayko re obt muscle thickness values	ETH.MESH.02019485	ETH.MESH.02019485
8/2/2010	Email Darlene Jane Kyle to Kathie Chen re Product Complaint CC1007047&CC1007048-Taiwan (TVTO:810081)	ETH.MESH.13206130	ETH.MESH.13206134
8/3/2010	Complaint Number: PI1-EWT0A6	ETH.MESH.14908783	ETH.MESH.14908783
8/3/2010	Complaint Number: PI1-F8GCTO	ETH.MESH.14967283	ETH.MESH.14967283
8/5/2010	Amin D email chain re Gynecare TVT Abbrevio advisory board members	ETH.MESH.09164480	ETH.MESH.09164481
8/6/2010	Clinical Evaluation Report, Robinson, Gynecare TVT Obturator System Tension-free Support for Incontinence	ETH.MESH.07219684	ETH.MESH.07219723
8/8/2010	Pagel K email re Prof Ed deck (draft 2 still) w/o video	ETH.MESH.01201955	ETH.MESH.01201956
8/11/2010	Hinoul P email re CER Abbrevio	ETH.MESH.00826026	ETH.MESH.00826027
8/11/2010	Hinoul Clinical Expert Report	ETH.MESH.00826028	ETH.MESH.00826045
8/16/2010	Email Brian Flynn to Jonathan Fernandez re permission	ETH.MESH.03432766	ETH.MESH.03432766
8/17/2010	Hinoul Clinical Expert Report	ETH.MESH.01795909	ETH.MESH.01795929
8/17/2010	MD&D Resolution Form	ETH.MESH.03497878	ETH.MESH.03497878
8/17/2010	Email Celine Heramza to Carolyn Brennan re Assignment "Product evaluation" has been closed for Issue #:10100122655	ETH.MESH.13210344	ETH.MESH.13210346
8/17/2010	Jaccard email chain re Particles in production w/attachment	ETH.MESH.13907355	ETH.MESH.13907355
8/17/2010	Clinical Expert Report Gynecare TVT Abbrevio	ETH.MESH.1795909	
8/24/2010	Email from Carlos E. Lugo-Ponce to Darlene Jane Kyle et al re Product Complaint CC1007005-Taiwan	ETH.MESH.01745568	ETH.MESH.01745572
8/30/2010	Wise E email chain re DoC for TVT Abbrevio	ETH.MESH.03654499	ETH.MESH.03654499
9/1/2010	Email Shalot Armstrong to Carlos E Lugo-Ponce re Product Complaint CC1007005-Taiwan	ETH.MESH.04101817	ETH.MESH.04101822
9/1/2010	Briceño Memo to DHF0000978 - TOPA re Preliminary Risk Analysis for TVT-O PA	ETH.MESH.06015227	ETH.MESH.06015229
9/2/2010	EWHU Incontinence EWHU Board Meeting Presentation - TVTO version 3	ETH.MESH.00751159	ETH.MESH.00751159

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9/10/2010	TVT-ABBREVO IFU 20100910	ETH.MESH.02341203	ETH.MESH.02341267
9/10/2010	TVTO-PA Clinical Strategy - Final Version	ETH.MESH.06923868	ETH.MESH.06923871
9/13/2010	Meier CER Mesh Erosions	ETH.MESH.03721328	ETH.MESH.03721449
9/13/2010	Customer Requirements Specification (CRS) for Project TVT-O PA Revision History	ETH.MESH.06917699	ETH.MESH.06917704
9/15/2010	DH0263-0278 DH0269: TVT (Tension Free Vaginal Tape) Factbook	ETH.MESH.1317508	ETH.MESH.1317613
9/16/2010	Interim (28 day) Report, PSE Accession No. 10-0126, Project No. 11730	HMESH_ETH_02041604	HMESH_ETH_02041626
9/21/2010	Paradise email chain re GYNecare TVT Obturator Sales: Feedback needed	ETH.MESH.09133724	ETH.MESH.09133725
9/25/2010	Hinoul Presentation - An anatomic comparison of the traditional TVT-O versus a modified TVT-O procedure	ETH.MESH.04933406	ETH.MESH.04933406
9/25/2010	Abbrevio Ad Board Notes	ETH.MESH.09218059	ETH.MESH.09218064
9/30/2010	Mahar K email chain re Key docs at AUGS	ETH.MESH.08344659	ETH.MESH.08344659
9/30/2010	Peebles R email re Transcription	ETH.MESH.09218058	ETH.MESH.09218058
10/1/2010	Flax C email chain re TVT Abbrevio material	ETH.MESH.00796051	ETH.MESH.00796052
10/4/2010	Elbert K email chain re hold for Abbrevio Lessons Learned	ETH.MESH.09970762	ETH.MESH.09970762
10/5/2010	Brennan email chain re 10100124625 etc. - MEMO re TVT-O particles	ETH.MESH.04101014	ETH.MESH.04101015
10/5/2010	Smith email chain re Need help on Sample Size for Stability Dimensions	ETH.MESH.07356789	ETH.MESH.07356790
10/6/2010	Hinoul P email chain re Abbrevio use in Leige	ETH.MESH.02599695	ETH.MESH.02599695
10/11/2010	Destefano C email re CR Approved: TVTA-474-10-10_12 Gynecare TVT Abbrevio Clinical Data Review Flashcard	ETH.MESH.09161482	ETH.MESH.09161484
10/11/2010	Christine Destefano email re Approved TVTAA-474-10-10_12 Gynecare TVT Abbrevio Clinical Data Review Flashcard	ETH.MESH.9161482	ETH.MESH.9161484
10/12/2010	The efficacy she needs with less mesh	ETH.MESH.02231537	ETH.MESH.02231538
10/18/2010	Linn email chain re Exception request for Abbrevio Professional education deck	ETH.MESH.00354234	ETH.MESH.00354234
10/25/2010	Zipfel R email re Anhalt - NY Times article - Trial of Synthetic Mesh in Pelvic Surgery Ends Early	ETH.MESH.00427910	ETH.MESH.00427910
10/27/2010	Revision Hx FM-0000167 Revision 4	ETH.MESH.03652924	ETH.MESH.03652955
10/28/2010	Hinoul P email chain re Dr. Waltregny contribution during Abbrevio training	ETH.MESH.02599885	ETH.MESH.02599886
11/2/2010	Process Qualification of FSMK0238 Revision 1	ETH.MESH.15257129	ETH.MESH.15257155
11/5/2010	Cecchini email chain re Ethicon DVD	ETH.MESH.11336648	ETH.MESH.11336648
11/8/2010	Innovation Council agenda	ETH.MESH.10132609	ETH.MESH.10132620
11/8/2010	TVT 20101108 Stop Coping Start Living . . .	ETH.MESH.6087471	ETH.MESH.6087472
11/9/2010	Krause email chain re Ethicon DVD	ETH.MESH.08516133	ETH.MESH.08516134
11/24/2010	TVT Abbrevio Dublin Meeting brochure	ETH.MESH.02596794	ETH.MESH.02596794

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11/30/2010	Robinson D email chain re Organization of EWHU Workshops	ETH.MESH.03259032	ETH.MESH.03259035
12/6/2010	Kirkemo A Dear Dr. unsolicited request for information letter	ETH.MESH.01226442	ETH.MESH.01226445
12/6/2010	Kirkemo A email re Your unsolicited request for medical information - MIR	ETH.MESH.01265511	ETH.MESH.01265511
12/6/2010	Patel email chain re TVT+M mesh question	ETH.MESH.09983201	ETH.MESH.09983201
12/9/2010	Henderson M email chain re Q4 Spend	ETH.MESH.05791132	ETH.MESH.05791133
12/9/2010	TVTR-566-10-11/12 Physician brochure - Gynecare TVT	ETH.MESH.06087513	ETH.MESH.06087514
12/9/2010	Irvin, M 12/08/2010 Post Call Notes	ETH.MESH.08041930	ETH.MESH.08041931
12/9/2010	Greg Prine email chain re New Gynecare TVT Abbrevio sales literature and DVD now available.	ETH.MESH.10237693	
12/9/2010	Vellucci email chain re Mesh and Biomechanical Data for TVTO-PA 510(k)	HMESH_ETH_07956799	HMESH_ETH_07956800
12/9/2010	Email re: 12/8 Post Call Notes	ETH.MESH.08041930	ETH.MESH.08041931
12/13/2010	MOntly Complaint Review November 2010	ETH.MESH.00540449	ETH.MESH.00540449
1/1/2011	Briefing Documents - Operation Abbrevio	ETH.MESH.11434367	ETH.MESH.11434379
1/13/2011	TVT-O Marketing video	ETH.MESH.02229061	ETH.MESH.02229061
1/16/2011	Presentation by Boris Batke (Associate Director, R&D): Chronic Pain - Prevention/future - Bioengineer's point of view	ETH.MESH.5916450	
1/18/2011	PA Consulting Group Mesh Erosion Interview Memo	ETH.MESH.07192412	ETH.MESH.07192414
1/20/2011	Physician Survey Results presentation	ETH.MESH.00791766	ETH.MESH.007911766
1/21/2011			
	RDLT 3 month post-launch close out - slide 12 Lessons ...	ETH.MESH.09936503	ETH.MESH.09936503
1/26/2011	Patient Brochure - Treatment Options for Stress Urinary Incontinence -- stop coping. start living.	ETH.MESH.08003303	ETH.MESH.08003318
2/1/2011	Master Consulting Agreement between Dr. Douglas Grier and Ethicon	ETH.MESH.05276184	ETH.MESH.05276194
2/7/2011	TVT-039-11-1/13 Patient brochure - stop coping. start living	ETH.MESH.08003295	ETH.MESH.08003302
2/8/2011	Dang email chain re K103727 - please advise	ETH.MESH.06016054	ETH.MESH.06016055
2/8/2011	Braskem msds 2011	ETH.MESH.10630803	ETH.MESH.10630808
2/10/2011	Beath email chain re Ethicon Mesh DVD - FDA Request Follow Up	ETH.MESH.05573254	ETH.MESH.05573254
2/11/2011	Letter from Pollard to Lin, date-stampede K103727 Trade Name: GYNECARE TVTO-PA Continence System	ETH.MESH.00206974	ETH.MESH.00206981
2/11/2011	Email Jennifer Haby to Sheelu Samuel re CR Aprvd: TVTA-088-11_TVT ABBREVO Prof Ed Slides Revised	ETH.MESH.03419391	ETH.MESH.03419391
2/13/2011	TVTA-083-11-2/13 - 1 Year RCT Trial Annotated Guide	ETH.MESH.02235375	ETH.MESH.02235387
2/14/2011	Roji A email re VOTE team 2010 1:1 calls	ETH.MESH.03981288	ETH.MESH.03981290

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2/15/2011	FDA Review of PFR and SUI Mesh Products - Changing Regulatory Environment and Potential Impact on Ethicon Pipeline - presentation	ETH.MESH.05604390	ETH.MESH.05604399
2/16/2011	Biomechanical consideration for Pelvic floor mesh design	ETH.MESH.02010834	ETH.MESH.02010855
2/19/2011	Mesh Processing Meshes Fabricated from Dissimilar Materials - Summary Document - Draft	ETH.MESH.22140265	ETH.MESH.22140266
2/21/2011	Lewis 2010 Performance and Development Plan Summary for O'Hara	ETHMESH.OHARA.00000347	ETHMESH.OHARA.00000353
2/22/2011	Voelker email chain re Approval of EMQD10: ECO354770	ETH.MESH.06165103	ETH.MESH.06165105
2/23/2011	Internal Notes - Memo	ETH.MESH.01216125	ETH.MESH.01216150
2/23/2011	Material Specification for TVT Prolene Polypropylene Mesh Roll Stock, Rev. 5	ETH.MESH.02219202	ETH.MESH.02219210
2/23/2011	Smith email chain re PC 10-029	ETH.MESH.15257127	ETH.MESH.15257128
2/24/2011	Email Jonathan Fernandez to Brian Flynn, et al. re Flynn contracts	ETH.MESH.08005908	ETH.MESH.08005909
2/28/2011	Gauld email re Here is the copy of FDA's letter (please do not forward)	ETH.MESH.00206973	ETH.MESH.00206973
2/28/2011	Kevin Frost email chain re SGS Fellows Symposium	ETH.MESH.08170224	ETH.MESH.08170232
3/1/2011	Presentation: ETHICON Polypropylene Mesh Technology by Boris Batke, Associate Director R&D	ETH.MESH.5479717	
3/2/2011	Hinoul email re Laser cut mesh tape	ETH.MESH.00576844	ETH.MESH.00576845
3/2/2011	Project TVTO PA SBT Stage Gate Chater Update Presentation	ETH.MESH.02238117	ETH.MESH.02238117
3/2/2011	Email re: Laser Cut Mesh Tape	ETH.MESH.00576844	ETH.MESH.00576845
3/7/2011	Garbarino S email chain re 2011 VOTE Team Conf Call - VOTE Team Questions	ETH.MESH.03898831	ETH.MESH.03898834
3/7/2011	Benjamin email re FDA ltt re 510k	ETH.MESH.06015196	ETH.MESH.06015196
3/8/2011	Papas N email chain re AUGS abstract	ETH.MESH.00575160	ETH.MESH.00575161
3/9/2011	Kirkemo A email re Abbrevio - initial holding force - MIR	ETH.MESH.02592466	ETH.MESH.02592466
3/9/2011	Kirkemo A Dear Dr. unsoliciated request for information letter	ETH.MESH.02592467	ETH.MESH.02592470
3/9/2011	Papas N email chain re AUGS Abstract	ETH.MESH.16434349	ETH.MESH.16434352
3/11/2011	Master Consulting Agreement between Brian J. Flynn and Ethicon	ETH.MESH.05276086	ETH.MESH.05276097
3/14/2011	Email Alyson Wess to Georgia Long, et al. re Incontinence PMT: 3/3 meeting notes	ETH.MESH.05163323	ETH.MESH.05163325
3/15/2011	Elaine Wise Product Monograph	ETH.MESH.12627553	ETH.MESH.12627577
3/15/2011	Kaminski email chain re Prosima Preparation	ETH.MESH.18846146	ETH.MESH.18846147
3/16/2011	Volpe email chain re TVT+M for Peter	ETH.MESH.05403773	ETH.MESH.05403773
3/17/2011	WEss A email chain re Incontinence PMT: 3/3 meeting notes	ETH.MESH.04062405	ETH.MESH.04062407

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3/28/2011	Proposed contents for TVTOPA Pre-IDE Meeting with FDA	ETH.MESH.06015198	ETH.MESH.06015198
3/29/2011	Frost K email re PF Summit Presentations	ETH.MESH.08969368	ETH.MESH.08969368
3/31/2011	Hinoult email chain re Workshop on Vaginal Tapes	ETH.MESH.07236294	ETH.MESH.07236295
3/31/2011	EWHU: Faculty Training - Sonoma CA Agenda	ETH.MESH.10818814	ETH.MESH.10818814
3/31/2011	Phillips, K email re Lack of quality engineering support for Prosima+M	ETH.MESH.11790162	ETH.MESH.11790162
3/31/2011	Letter by Piet Hinoul, Medical Affairs Director, re Workshop on Vaginal Tapes	ETH.MESH.7236294	ETH.MESH.7236297
4/1/2011	Ethicon 2011 Incontinence & Pelvic Floor Summit agenda	ETH.MESH.10818815	ETH.MESH.10818816
4/1/2011	Gerin-Roze email chain re TVT-S Lot related to NCR11-01867	ETH.MESH.11770891	ETH.MESH.11770892
4/2/2011	Email re: IR11040517: Degradation Evaluation of TVT SECUR	ETH.MESH.11076345	ETH.MESH.11076346
4/4/2011	DRAFT - PA Strategy Review presentation	ETH.MESH.01201047	ETH.MESH.01201068
4/6/2011	Hoffman S email chain re 6 weeks into Abbrevo Launch	ETH.MESH.10224489	ETH.MESH.10224490
4/7/2011	Ethicon 360 Gynecare TVT Abbrevo uses a refined obturator procedure so that you can use less mesh with confidence	ETH.MESH.05572669	ETH.MESH.05572669
4/10/2011	Feinberg email chain re TVTO PA full team meeting minutes, Thursday April 7th	ETH.MESH.09982887	ETH.MESH.09982888
4/19/2011	Monthly Complaint Review	ETH.MESH.00540629	ETH.MESH.00540629
4/21/2011	Frost K email re 2011 Incontinence & Pelvic floor REcap	ETH.MESH.10818812	ETH.MESH.10818813
4/22/2011	TVTOPAC Cadaver Lab Report	ETH.MESH.02218436	ETH.MESH.02218439
4/25/2011	Briceno J email re 1st Post PRA review TVT Abbrevo	ETH.MESH.01216122	ETH.MESH.01216122
4/25/2011	Briceño J Memo re TVT Abbrevo - Risk Assessment Review	ETH.MESH.01216123	ETH.MESH.01216124
4/26/2011	Smith email re TVT+M mesh	ETH.MESH.06165243	ETH.MESH.06165243
4/29/2011	Holloway email chain re Removal of TVT-O system due to severe neuropathic leg pain - MIR	ETH.MESH.13284086	ETH.MESH.13284088
5/12/2011	Decker R email re Abbrevo letter	ETH.MESH.07954867	ETH.MESH.07954867
5/13/2011	Email Laura Hutto to Brian Luscombe re Flynn	ETH.MESH.05822684	ETH.MESH.05822693
5/13/2011	Decker R email chain re Abbrevo letter	ETH.MESH.07954703	ETH.MESH.07954705
5/16/2011	US EWHU Executive Performance Review Presentation	ETH.MESH.03643726	ETH.MESH.03643726
5/16/2011	Ona Bernal email chain re Week 1: TVT Abbrevo Eval	ETH.MESH.11445930	
5/18/2011	PA Consulting Group Report: Investigating Mesh Erosion in Pelvic Floor Repair	ETH.MESH.02589032	ETH.MESH.02589079
5/18/2011	Berman, Robinson, Wang, Rhodes - Report - Investigating Mesh Erosion in Pelvic Floor Repair	ETH.MESH.03750903	ETH.MESH.03750950
5/18/2011	Investigating Mesh Erosion in Pelvic Floor Repair	ETH.MESH.2589032	ETH.MESH.2589079

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5/18/2011	PA Consulting Group - Investigating Mesh Erosion in Pelvic Floor Repair - Power Point	ETH.MESH.02589032	ETH.MESH.02589079
5/26/2011	Project NEO - DHF0000979 Medical Affairs NEO DRM Rationales	ETH.MESH.02030340	ETH.MESH.02030356
5/30/2011	Spreadsheet listing microporous, medium and macroporous meshes	ETH.MESH.5479535	
6/2/2011	Holloway email chain re TVT-O medial and lateral leg pain - MIR CHATS # 10100143432	ETH.MESH.13213760	ETH.MESH.13213766
6/6/2011	CA to audit abbrevo(1)	ETH.MESH.08776497	ETH.MESH.08776521
6/7/2011	Jones S email re conference call on converting an outside in user to Abbrevo	ETH.MESH.17556602	ETH.MESH.17556603
6/8/2011	O'Connell email chain re Articles of Mesh Properties	ETH.MESH.00185184	ETH.MESH.00185184
6/11/2011	PA Consulting Group - Investigating Mesh Erosion in Pelvic Floor Repair - Power Point	ETH.MESH.07903941	ETH.MESH.07903988
6/22/2011	Berman, Robinson, Wang, Rhodes Investigating Mesh Erosion in Pelvic Floor Repair presentation	ETH.MESH.07192929	ETH.MESH.07192977
6/30/2011	Affeld, T email chain re PS vs +M	ETH.MESH.07903682	ETH.MESH.07903683
7/6/2011	Miller D email chain re Prolift professional education	ETH.MESH.05337217	ETH.MESH.05337220
7/6/2011	Luscombe B email chain re request from Miller re lecture material	ETH.MESH.05337225	ETH.MESH.05337228
7/6/2011	Dennis Miller, MD email chain re pore classification	ETH.MESH.5337217	
7/12/2011	Scion SBT Presenation - slide 9 - Abbrevo COGS, ASP, GP...	ETH.MESH.00996929	ETH.MESH.00996929
7/12/2011	slide 19 Abbrevo COGS, ASP. GP	ETH.MESH.06921562	ETH.MESH.06921562
7/13/2011	Email Bridget Ross (WW President, EWH&U) re FDA Health Notification	ETH.MESH.02253078	ETH.MESH.02253079
7/29/2011	Email Vijay Madikonda re BSI Technical File Audit - July 28-29, 2011	ETH.MESH.00301367	ETH.MESH.00301369
8/4/2011	Lin Itt FDA re K103727 Gynecare TVTO-PA Continence System - Request for Withdrawal of 510k	ETH.MESH.07455424	ETH.MESH.07455425
8/4/2011	Gynecare RVTO-OA - Request for Withdrawal of 510k	ETH.MESH.10635251	ETH.MESH.10635515
8/8/2011	TOPA withdraw confirmation	ETH.MESH.20006789	ETH.MESH.20006791
8/16/2011	Draft - Matrix 1,2 -- Tissue Bulking Material, Methods, and Devices (external bulking)	ETH.MESH.22140235	ETH.MESH.22140238
8/26/2011	Karl J email chain re Braskem. . . A Little History	ETH.MESH.06261965	ETH.MESH.06261967
8/30/2011	Samuel S email re Mesh Data	ETH.MESH.11175841	ETH.MESH.11175842
10/6/2011	Email Libby Lewis to Mary Byerly re Western Region Needs	ETH.MESH.11445493	ETH.MESH.11445494
10/12/2011	Clinical Registry Report - Protocol Number: 300-06-006	ETH.MESH.02877814	ETH.MESH.02881493
11/1/2011	Smith Memo re Scion SIS develoment history summary; VOC, Human factors, Cadaver labs, Internal R&D	ETH.MESH.06857127	ETH.MESH.06857132
11/9/2011	AAGL Las Vegas meeting brochure	ETH.MESH.00107688	ETH.MESH.00107688

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11/16/2011	Draper S email re Initial Letter to Manufacturer MHRA Re. . .	ETH.MESH.03488556	ETH.MESH.03488564
12/2/2011	Henderson email - Gynecologic and Obstetric Investigation (1983) Abstract	ETH.MESH.15354959	ETH.MESH.15354959
12/6/2011	PLT 12 month post-launch close out PPT - slide 17 Executive Summary.	ETH.MESH.09977270	ETH.MESH.09977271
12/10/2011	London Memo to Parisi and Mahar re VOC on new laser Cut TVT Mesh	ETH.MESH.1809082	ETH.MESH.1809083
1/16/2012	Draft - Uniform three dimensional tissue scaffold of absorbable and non-absorbable materials	ETH.MESH.22140231	ETH.MESH.22140234
2/1/2012	Postmarket Surveillance Plan: PS120095 GYNECARE TVT Secure System KO52401	ETH.MESH.04474763	ETH.MESH.04474770
2/1/2012	Grier Consulting Agreement Requisition Form	ETH.MESH.09155883	ETH.MESH.09155895
2/1/2012	Consulting Agreement Requisition Form - Part I Ethicon and Melvyn A. Anhalt	ETH.MESH.09155909	ETH.MESH.09155920
2/16/2012	PowerPoint - EWHU Incontinence 2012 Pipeline Refresh	ETH.MESH.03644217	ETH.MESH.03644217
2/24/2012	Lapinskas, I, email chain originating re Discussion of 3.5 mil Prolene production	ETH.MESH.07730291	ETH.MESH.07730295
2/28/2012	Hinoult P email chain re CER Abbrevio CER	ETH.MESH.07226914	ETH.MESH.07226963
3/1/2012	Batke B email chain re AGES Pelvic Floor Conference - Gala Dinner Invitation	ETH.MESH.04015102	ETH.MESH.04015104
3/1/2012	Vellucci, L email chain re Polypropylene Mesh	ETH.MESH.07226377	ETH.MESH.07226379
3/5/2012	Savidge email chain re TVT-O mesh weight	ETH.MESH.07502642	ETH.MESH.07502645
3/6/2012	Response to MHRA inquiry regarding inertness of polypropylene mesh	ETH.MESH.07455220	ETH.MESH.07455221
3/7/2012	Issues Report Run Between 10/01/2010 and 02/14/2012	ETH.MESH.02652179	ETH.MESH.02652317
3/11/2012	PV Minutes of TAM meeting	ETH.MESH.13886781	ETH.MESH.13886782
3/12/2012	Hinoult P email chain re Patient complication in Wichita, KS	ETH.MESH.05998775	ETH.MESH.05998778
3/12/2012	Savidge, et al response to email from Huntington re 'Clave' publication	ETH.MESH.07205369	ETH.MESH.07205370
3/14/2012	Independent MD&D Sector Audit by QualityHub, Inc. Pore size	ETH.MESH.07724068	ETH.MESH.07724080
3/15/2012	Innovations in Mesh Development by Boris Batke	ETH.MESH.04037600	ETH.MESH.04037600
3/25/2012	The efficacy she needs with less mesh	ETH.MESH.13681529	ETH.MESH.13681532
4/2/2012	DeLeval J email re Alerte TVT Abbrevio	ETH.MESH.03941623	ETH.MESH.03941623
4/2/2012	Hinoult P email chain re Prof de Leval - TVT Abbrevio	ETH.MESH.04938298	ETH.MESH.04938299
4/2/2012	Hinoult P email chain re Alerte TVT Abbrevio	ETH.MESH.05998811	ETH.MESH.05998812
4/2/2012	Barnes C email chain re Ethicon Gynecare Innovations Event	ETH.MESH.17556496	ETH.MESH.17556497
4/3/2012	deLeval J email re Alerte TVT Abbrevio	ETH.MESH.03941617	ETH.MESH.03941618
4/3/2012	Hinoult P email chain re Alerte TVT Abbrevio	ETH.MESH.03941621	ETH.MESH.03941622
4/3/2012	Hinoult P email chain re Alerte TVT Abbrevio	ETH.MESH.05998803	ETH.MESH.05998804

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4/3/2012	Hinour P email chain re Alerte TVT Abbrevio	ETH.MESH.05998805	ETH.MESH.05998806
4/3/2012	Hinoul P email chain re Alerte TVT Abbrevio	ETH.MESH.05998807	ETH.MESH.05998808
4/3/2012	Peebles R email chain re Alerte TVT Abbrevio	ETH.MESH.09227440	ETH.MESH.09227441
4/3/2012	Beccia N email chain re Alerte TVT Abbrevio	ETH.MESH.10051284	ETH.MESH.10051286
4/3/2012	Pitts L email chain re Alerte TVT Abbrevio	ETH.MESH.10051331	ETH.MESH.10051333
4/3/2012	Prine G email chain re Alerte TVT Abbrevio	ETH.MESH.12730858	ETH.MESH.12730860
4/3/2012	Barnes C email chain re ACT REQ: Urgent quick need request	ETH.MESH.17556511	ETH.MESH.17556511
4/3/2012	Email re: ALERTE TVT ABBREVO	ETH.MESH.03941617	ETH.MESH.03941618
4/4/2012	Steele J email chain re Alerte TVT Abbrevio	ETH.MESH.03985932	ETH.MESH.03985934
4/4/2012	Langen B email re SMII Welcome Letter	ETH.MESH.17556512	ETH.MESH.17556512
4/5/2012	Hinoul P email chain re Alerte TVT Abbrevio	ETH.MESH.05998816	ETH.MESH.05998818
4/5/2012	Hinoul P email chain re Alerte TVT Abbrevio	ETH.MESH.05998819	ETH.MESH.05998820
4/5/2012	Luscombe B emial re Brand Team for Inc POP	ETH.MESH.17556486	ETH.MESH.17556487
4/11/2012	Hinoul P email chain re Alerte TVT Abbrevio	ETH.MESH.05998821	ETH.MESH.05998823
4/12/2012	Ethicon Gynecare Innovations flyer	ETH.MESH.17556498	ETH.MESH.17556498
4/27/2012	Hinoul P email chain re slings at surgery center	ETH.MESH.05572526	ETH.MESH.05572528
4/27/2012	Barnes C email chain re Ty Erickson Adobe Connect's with Abbrevio	ETH.MESH.17556538	ETH.MESH.17556539
4/30/2012	Peebles, R email chain re Alerte TVT Abbrevio	ETH.MESH.09227438	ETH.MESH.09227439
5/1/2012	Pramudji fax re Contract	ETH.MESH.08066401	ETH.MESH.08066414
5/10/2012	Hinoul P email chain re Alerte TVT Abbrevio	ETH.MESH.05998835	ETH.MESH.05998836
5/13/2012	de Leval J email chain re Alerte TVT Abbrevio	ETH.MESH.07318311	ETH.MESH.07318313
5/14/2012	Vellucci email re 522 Guidance Document Gynecare Proxima	ETH.MESH.05600730	ETH.MESH.05600731
5/15/2012	Master Consulting Agreement between Melvyn A. Anhalt and Ethicon	ETH.MESH.08065931	ETH.MESH.08065943
5/15/2012	ETHICON GYNECARE U.S. Commercialization Decision	ETH.MESH.05598522	
5/29/2012	Background Information Gynecare Pelvic Floor Repair Products and Gynecare TVT Scruce	ETH.MESH.05600916	ETH.MESH.05600923
5/29/2012	ETHICON GYNECARE WW Commercialization Decision	ETH.MESH.05675500	
6/4/2012	PFT / TVT Secur Discontinuation: Current State - Presentation	ETH.MESH.19223769	ETH.MESH.19223773
6/14/2012	TVT-172-12-6/14 Patient Brochure - Stop Coping. START LIVING. WHAT YOU SHOULD KNOW ABOUT STRESS URINARY INCONTINENCE	ETH.MESH.05815791	ETH.MESH.05815802
6/16/2012	ARTISYN Advisory Board notes	ETH.MESH.09158424	ETH.MESH.09158430
7/26/2012	Email Piet Hinoul to Axel Arnaud re article "The perils of commercially driven surgical innovation"	ETH.MESH.05125293	ETH.MESH.05125297
8/6/2012	Work Instructions for In-Process & Finished Goods Defect Classifications for Ethicon Products, Appendix 8 - Mesh	ETH.MESH.13376756	ETH.MESH.13376758
8/6/2012	Primary Blister Defect Definitions and Classifications Release Level: 4. Production	ETH.MESH.13376759	ETH.MESH.13376768
8/7/2012	Chen M email chain re New Complaint Form 23125	ETH.MESH.09478633	ETH.MESH.09478636

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8/7/2012	Doyle email chain re Surgeon request for follow up 10100175641	ETH.MESH.11529265	ETH.MESH.11529266
8/20/2012	Chen M email chain re Urgent - MDR serious injuries Gynecare France	ETH.MESH.09478684	ETH.MESH.09478688
9/25/2012	Gynecare PROLIFT +M Pelvic Floor Repair System	ETH.MESH.8315779	ETH.MESH.8315810
9/28/2012	Letter Benjamin R. Fisher PhD (Department of Health & Human Services) to Susan Lin re Gynecare TVT Abbrevio Continence System K100936 re marketing device	ETH.MESH.10039685	ETH.MESH.10040061
10/1/2012	Gynecare TVT Abbrevio Salees Aid TVTA 325-12	ETH.MESH.13681528	ETH.MESH.13681528
10/15/2012	TVT 20121015 Stop Coping Start Living . . .	ETH.MESH.9744848	ETH.MESH.9744855
12/10/2012	TVT 20121210 Stop Coping Start Living . . .	ETH.MESH.9744858	ETH.MESH.9744863
1/6/2013	Amin D Gynecare Protfolio Presentation	ETH.MESH.03685918	ETH.MESH.03685925
1/11/2013	Chung email chain re Gynecare RFP	ETH.MESH.13374555	ETH.MESH.13374558
1/21/2013	Tait email chain re Non conform lids	ETH.MESH.14348386	ETH.MESH.14348388
1/30/2013	CAPA-002157	ETH.MESH.15137959	ETH.MESH.15137967
2/14/2013	TVT 20130214 Stop Coping Start Living . . .	ETH.MESH.9744840	ETH.MESH.9744845
2/15/2013	Connaughton email chain re New litigation Prolift & TVT	ETH.MESH.13274846	ETH.MESH.13274847
2/18/2013	Journot memo re CAPA130022 - Defective percentage justification	ETH.MESH.15137979	ETH.MESH.15137979
2/23/2013	Roseleip email chain re TVT Heads up	ETH.MESH.08422124	ETH.MESH.08422125
3/8/2013	CAPA#130022 - Repetition of NCR for particles - Team Meeting Minutes	ETH.MESH.15137986	ETH.MESH.15137987
3/20/2013	Revision History of MS-0000108	ETH.MESH.10633520	
3/20/2013	Connaughton email chain re New litigation TVT	ETH.MESH.13208194	ETH.MESH.13208196
3/26/2013	Rahman communication - AUGS Issues Statement Opposing the Restriction of Surgical Options for Pelvic Floor Disorders	ETH.MESH.08073801	ETH.MESH.08073803
4/23/2013	IFU Index and Production Bates Range Chart	ETH.MESH.02341954	ETH.MESH.02341954
4/25/2013	IFU Index and Production Bates Range Chart	ETH.MESH.02342194	ETH.MESH.02342194
4/26/2013	Clinical Expertise - The Evolution of Sub-urethral Slings for the Surgical Corrector of Female Stress Urinary Incontinence (SUI) Obturator	ETH.MESH.13739540	ETH.MESH.13739540
5/3/2013	TVT 20130503	ETH.MESH.09744870	ETH.MESH.09744871
5/3/2013	Hinoul Clinical Evaluation Report	ETH.MESH.10287104	ETH.MESH.10287439
5/3/2013	TVT 20130503 Gynecare TVT Obturator - Mesh Placement for Patient Consult	ETH.MESH.9744870	ETH.MESH.9744871
5/7/2013	TVT 20130507 Gynecare TVT Abbrevio - Mesh Placement for Patient Consult	ETH.MESH.9744866	ETH.MESH.9744867

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5/8/2013	Biocompatibility Risk Assessment Report for Gynecare TVT Product Family	ETH.MESH.09909830	ETH.MESH.09909882
5/22/2013	GGM Blue Database Export TVT Obturator Brochure	ETH.MESH.13700031	ETH.MESH.13700032
5/23/2013	Connaughton email chain re New litigation	ETH.MESH.13259844	ETH.MESH.13259845
6/5/2013	McNelis email re new litigation TVT & Prosima	ETH.MESH.14852591	ETH.MESH.14852592
6/5/2013	McNelis email re new litigation TVT & Prosima	ETH.MESH.14901756	ETH.MESH.14901757
6/13/2013	Journot email chain re Design Impact assessment ADAPTIV - Creation of change project	ETH.MESH.13457716	ETH.MESH.13457718
6/19/2013	Issue Reports Open Date BEtween 01-Jan-2005 and 02-Jun-2013	ETH.MESH.09732998	ETH.MESH.09733718
6/19/2013	GGM Blue Database Export Project ID: 417127 TVTO-426-13	ETH.MESH.13704931	ETH.MESH.13704932
6/21/2013	Weisberg email chain re TVT mesh elongation FW: Dr. Kenny Maslow	ETH.MESH.12910023	ETH.MESH.12910026
6/21/2013	Weisbert email chain re TVT mesn elongation FW: Dr. Kenny Maslow	ETH.MESH.12910030	ETH.MESH.12910032
6/25/2013	Weisberg email chain re TVT mesh enlongation - Redacted	ETH.MESH.12910111	ETH.MESH.12910113
6/27/2013	Ex T-722 Mltchell - Clinical Expert Report Gynecare Prolift +M	ETH.MESH.08315779	ETH.MESH.08315810
7/2/2013	Connaughton email chain re new litigation TVT-O	ETH.MESH.14908784	ETH.MESH.14908785
7/15/2013	Connaughton email chain re New litigation TVT-O	ETH.MESH.14967284	ETH.MESH.14967285
7/19/2013	Clinical Evaluation Report Gynecare TVT Family of Products	ETH.MESH.10150515	ETH.MESH.10150849
8/5/2013	Amin email chain re HPG Pelvic Floor RFP	ETH.MESH.12877116	ETH.MESH.12877117
8/19/2013	Finch email chain re New litigation TVT-S	ETH.MESH.13292806	ETH.MESH.13292807
8/28/2013	Hinoul email re MIR TVT - ilioninguinal pain w/attachment	ETH.MESH.12913351	ETH.MESH.12913356
9/17/2013	Librojo email chain re Copy Review Exception	ETH.MESH.12906504	ETH.MESH.12906506
9/21/2013	Gallo email chain re new litigation TVT	ETH.MESH.13296239	ETH.MESH.13296240
9/26/2013	CAPA File - Protocol to migrate CAPAs from PLM to ETQ Application	ETH.MESH.15137968	ETH.MESH.15137968
9/30/2013	Angelini Browse JJEDS Object Detail form	ETH.MESH.10591939	ETH.MESH.10591949
11/7/2013	Jacobs email chain re defect to harms map	ETH.MESH.12907174	ETH.MESH.12907174
11/7/2013	McNelis email new litigation TVT	ETH.MESH.15034561	ETH.MESH.15034562
11/9/2013	Finch email re new litigation TVT	ETH.MESH.14896228	ETH.MESH.14896229
12/8/2013	Finch email chain re Addtl Info New Litigation Prosima & TVT-O	ETH.MESH.14913573	ETH.MESH.14913575
12/8/2013	Finch email chain re Addtl Info new litigation Prosima & TVT-O	ETH.MESH.14994654	ETH.MESH.14994656
1/6/2014	Killins email chain re Addtl info - new litigation TVT & Prosima	ETH.MESH.14852593	ETH.MESH.14852595
1/8/2014	TVTO_366_13_TVT Obturator Brochure	ETH.MESH.13700033	ETH.MESH.13700037
1/9/2014	Corrado email re QRB presentation	ETH.MESH.17640736	ETH.MESH.17640767
1/10/2014	Hinoul P email re Abbrevio MIR	ETH.MESH.16359412	ETH.MESH.16359412

DOCUMENTS

1/30/2014	Tran email chain re addtl info - Prosima & TVT-O	ETH.MESH.14913576	ETH.MESH.14913578
1/30/2014	Tran email chain re Addtl Info -	ETH.MESH.14994657	ETH.MESH.14994659
1/31/2014	Jackson email chain Addtl Info -	ETH.MESH.14967286	ETH.MESH.14967287
2/3/2014	Mesh Slide T-3581	ETH.MESH.00584179	ETH.MESH.00584179
2/4/2014	Piper email chain re Addtl info	ETH.MESH.14896230	ETH.MESH.14896232
2/6/2014	Sedlatschek email chain re Secant Medical Inquiry on Gynecare Mesh Products	ETH.MESH.16357097	ETH.MESH.16357097
2/7/2014	Tran email chain re addtl info 1/30/14	ETH.MESH.14896233	ETH.MESH.14896235
2/7/2014	Sedlatschek email re Secant Medical Inquiry on Gynecare Mesh Products	ETH.MESH.17777763	ETH.MESH.17777768
2/27/2014	Revision Hx 100193881	ETH.MESH.22852060	ETH.MESH.22852063
3/26/2014	Rodriguez email chain re Nilsson 2013	HMESH_ETH_06033196	HMESH_ETH_06033202
3/27/2014	Rodriguez email chain re Secant Medical Inquiry on Gynecare Mesh Products	ETH.MESH.17619399	ETH.MESH.17619405
4/7/2014	Dear Dr. Itr re unsolicited request for medical/scientific information - Gynecare TVT Abbrevio	ETH.MESH.16354541	ETH.MESH.16354545
4/11/2014	Hinour P email chain re TVT Abbrevio medical information request	ETH.MESH.16359598	ETH.MESH.16359598
4/14/2014	PQI Revision 10	ETH.MESH.17642669	ETH.MESH.17642686
4/14/2014	Elbert email chain re Candad - TVT RFQ	ETH.MESH.19125383	ETH.MESH.19125385
5/19/2014	Rodriguez email chain re UPDATE to Escalation Notice - Section 39 Request - TVT, Gynemesh PS & Artisyn Y-Shared Mesh	ETH.MESH.17777759	ETH.MESH.17777762
10/2/2014	Smith email re TVT Products	ETH.MESH.19125531	ETH.MESH.19125531
2/17/2015	List of Preceptor Names and Events Attended	ETH.MESH.03625982	ETH.MESH.03625982
6/1/2015	Ethicon UK Gynaecology Complaints email re Customer Ref 2015/005/020/104/005 Request for Information	ETH.MESH.22646295	ETH.MESH.22646296
5/7/2016	Continence Health European Experts Meeting - Power Point	ETH.MESH.02313931	
??/??/02	CER Update for TVT	ETH.MESH.00340836	ETH.MESH.00340838
??/??/02	Hellhammer et al. Scientific Statement - Shrinking Meshes?	ETH.MESH.05446129	ETH.MESH.05446132
??/??/03	Contact Points - Nummular allergic contact dermatitis after scabies treatment, R. Kaminska, et al	HMESH_ETH.07269753	HMESH_ETH.07269765
??/??/07	Brochure "Find out how to stop urine leakage like Bonnie did"	ETH.MESH.00163582	ETH.MESH.00163597
??/??/07	Gynecare TVT Secur Competitive Product Update	ETH.MESH.01805958	ETH.MESH.01805958
??/??/07	Basell Purell MSDS	ETH.MESH.06861946	ETH.MESH.06861946
??/??/07	TVT 20070531 Patient Brochure - The Choice to End Stress Urinary Incontinence Find out how to stop urine leakage like Bonnie did	ETH.MESH.08003247	ETH.MESH.08003262
??/??/08	Brochure The Gynecare TVT Family of Products 3 SUI Solutions. Delivering Data, Safety & Choice.	ETH.MESH.00658453	ETH.MESH.00658458

DOCUMENTS

??/??/08	ANSI/AAMI/ISO 10993-7:2008	ETH.MESH.07474296	ETH.MESH.07474407
??/??/09	Stop coping. Start living	ETH.MESH.00002162	ETH.MESH.00002177
??/??/09	P15506 Gynecare TVT IFU	ETH.MESH.02340402	ETH.MESH.02340470
??/??/10	The efficacy she needs with less mesh - TVT Abbrevio	ETH.MESH.00270802	ETH.MESH.00270821
??/??/10	2010 preceptor payments spreadsheet	ETH.MESH.00499024	ETH.MESH.00499024
??/??/10	Physician patient follow-up form letter	ETH.MESH.02236784	ETH.MESH.02236785
??/??/10	R&D CO-OP Welcome Guide Spring 2010	ETH.MESH.06260647	ETH.MESH.06260671
??/??/10	The efficacy she needs with less mesh - TVT Abbrevio	ETH.MESH.08614017	ETH.MESH.08614021
??/??/11	Ozog, Yves Doctorial Thesis: Theoretical and Experimental Evaluation of Implant Materials Used in Pelvic Organ Prolapse Repair	ETH.MESH.04005863	ETH.MESH.04006038
??/??/11	2011 Price List	ETH.MESH.17556578	ETH.MESH.17556579
??/??/12	Sales spreadsheet	ETH.MESH.08078799	ETH.MESH.08078799
??/??/12	TVT-312-12 Patient Brochure - stop coping. start living. GYNECARE TVT Family of Products	ETH.MESH.09744848	ETH.MESH.09744855
??/??/13	TVT-131-13 Patient Brochure - stop coping start living. What You Should Not About Stress Urinary Incontinence	ETH.MESH.09744840	ETH.MESH.09744845
??/??/13	TVT Abbrevio information pamphlet	ETH.MESH.09744866	ETH.MESH.09744867
??/??/14	Product cost analysis	ETH.MESH.06767981	ETH.MESH.06767983
??/??/14	Total Units Sold Chart	T-1499	T-1499
??/??/2002	Copy Review Submission Form	ETH.MESH.00143539	
??/??/2005	Gynecare TVT SECUR System Tension-free Support for Inc	ETH.MESH.02340568	ETH.MESH.02340755
??/??/2005	Gynecare TVT Obturator System Tension-free Support for Incontinence - Instructions for Use	ETH.MESH.02340902	ETH.MESH.02340908
??/??/2006	Product Pointer	ETH.MESH.00746209	ETH.MESH.00746209
??/??/2006	A 3-month preclinical trial to assess the performance of a new TVT-like mesh (TVTx) in a sheep model. Int Urogynecol J - DOI 10.1007/s00192-006-0130-x	ETH.MESH.00034720	ETH.MESH.00034724
??/??/2008	Procedural Steps - Gynecare TVT Secur System	ETH.MESH.01128679	ETH.MESH.01128698
??/??/2008	Brochure for Gynecare TVT - Stop Coping. Start Living.	ETH.MESH.08003279	ETH.MESH.08003294
??/??/2009	Mini TVT-O Claim Development	ETH.MESH.00345842	ETH.MESH.00345842
??/??/2009	Gynecare TVT Tension-free Vaginal Tape System - Instructions for Use	ETH.MESH.03427878	ETH.MESH.03427883
??/??/2010	Draft 510(k) premarket Abbrevio	ETH.MESH.00343379	ETH.MESH.00343442
??/??/2010	The efficacy she needs with less mesh - annotated - round 3	ETH.MESH.00346194	ETH.MESH.00346201
??/??/2010	The efficacy she needs with less mesh	ETH.MESH.11434264	ETH.MESH.11434272
??/??/2010	Midterm Prospective Evaluation of TVT-Secur Reveals High Failure Rate. European Urology 58 (2010) 157-161	ETH.MESH.01248510	ETH.MESH.01248514
??/??/2011	Competitive Dissection Flashcard	ETH.MESH.00790545	ETH.MESH.00790546
??/??/2011	Ethicon Neuchâtel A changing Product Portfolio	ETH.MESH.14273633	ETH.MESH.14273668
??/??/2012	Frequently Asked Questions Clinical Data Review 3-Year Data Flashcard	ETH.MESH.07808484	ETH.MESH.07808486

DOCUMENTS

??/??/2012	DSL Clinical Article Waltregny - New Surgical Technique for Tx of SUI TVT-Abbrevio . . .	ETH.MESH.16289560	ETH.MESH.16289569
??/??/2012	Evaluation of the Fixation of Gynecare TVT Abbrevio Continence System as Compared to Gynecare TVT Obturatory System Tension-Free Support for Incontinence in Human Cadaveric Model - Presentaiton	ETH.MESH.16426660	ETH.MESH.16426660
??/??/2013	Patient Brochure	ETH.MESH.16308087	ETH.MESH.16308090
00/0/0000	Consultancy Agreement	ETH.MESH.9748842	ETH.MESH.9748846
00/00/0000	Gynecare TVT Patient Brochure stop coping. start living	ETH.MESH.2236580	ETH.MESH.2236595
00/00/0000	Spanish Gynecare TVT Patient Brochure, translated from Gynecare TVT English Patient Brochure	ETH.MESH.2237665	ETH.MESH.2237696
00/00/0000	Definition for Major Invasive Surgeries	ETH.MESH.321804	ETH.MESH.321805
00/00/0000	Gynecare Pro-lift Ad.	ETH.MESH.3905968	
00/00/0000	Medscand Agreement Files	ETH.MESH.8696085	ETH.MESH.8696134
00/00/0000	Consultancy Agreement	ETH.MESH.9748848	ETH.MESH.9748853
00/00/2002	CER Update for TVT 06/15/2000	ETH.MESH.340836	ETH.MESH.343838
00/00/2004	Memo from London Brown to D. Smith re Mechanical Cut vs. Laser Cut Mesh Rationale	ETH.MESH.858252	ETH.MESH.858253
00/00/2007	Gynecare TVT Secure Competitive Produce Update 2007 Power Point Presentation	ETH.MESH.1805958	
00/00/2007	PE GF 4750 Purell PP technical data info	ETH.MESH.6861946	
00/00/2008	ANSI/AAMI/ISO 10993-7:2008 EO residual ISO testing American National Standard Biological evaluationof medical devices--Part 7: Ethylene oxide sterilization residuals	ETH.MESH.7474296	ETH.MESH.7474407
00/00/2010	Physician patient follow-up form letter	ETH.MESH.2236784	ETH.MESH.2236785
00/00/2011	Ozog, Yves Doctorial Thesis: Theoretical and Experimental Evaluation of Implant Materials Used in Pelvic Organ Prolapse Repair	ETH.MESH.4005863	
00/00/2012	TVT 2012 Stop Coping Start Living . . . TVT-172-12-6/14	ETH.MESH.5815791	ETH.MESH.5815802
01/??/02	DTC Advertising Patient Potential January 2002 Presentation	ETH.MESH.08793554	ETH.MESH.08793554
01/??/08	Working copy - Communications to Surgeons re TVT SECUR	ETH.MESH.00318311	ETH.MESH.00318312
02/??/02	5 Years of Proven Performance TVT Sales Aid (TVT041)	ETH.MESH.00339437	ETH.MESH.00339442
03/??/02	Worldwide Clinical Trials, Medical Affairs Gynecare - Monthly Report	ETH.MESH.07387082	ETH.MESH.07387103
03/??/07	CAPA 070015 Trending and tracking system - presentation	ETH.MESH.14708986	ETH.MESH.14709011

DOCUMENTS

03/??/11	ETHICON Polypropylene Mesh Technology- Batke presentation	ETH.MESH.05479717	ETH.MESH.05479717
04/??/00	European Clinical R&D Monthly Report	ETH.MESH.05493782	ETH.MESH.05493810
04/??/08	Klosterhalfen Interim report mesh explants pelvic floor repair	ETH.MESH.00006636	ETH.MESH.00006636
04/??/1989	Ethicon, Inc. Book No. 3077	ETH.MESH.15143734	ETH.MESH.15143821
05/??/12	Quality Operation Review Trend Analysis Metrics - presentation	ETH.MESH.22754103	ETH.MESH.22754142
06/??/00	TVT Surgeons Resource Monograph	ETH.MESH.00400957	ETH.MESH.00400978
06/??/02	Monthly Report WW Clinical Research Activities Gynecare	ETH.MESH.05490280	ETH.MESH.05490311
07/??/09	BUC July 2009 I&pf platforms	ETH.MESH.05764101	ETH.MESH.05764101
07/??/12	FDA Communication re PS120095 GYNECARE TVT Secur System - Amended: 05032012	ETH.MESH.11333804	ETH.MESH.11333805
07/??/2012	Claims for Gynecare TVT Abbrevio spreadsheet	ETH.MESH.00346665	ETH.MESH.00346667
08/??/09	HS Study Monthly Update	ETH.MESH.00533025	ETH.MESH.00533026
08/??/2010	Clinical Data Review Presented at ICS/IUGA Aug 2010	ETH.MESH.03422160	ETH.MESH.03422162
09/??/04	Physician Segmentation Study for Gynecare TVT Final Presentation - Copernicus	ETH.MESH.03571983	ETH.MESH.03572098
09/??/07	Pleiger - Polyamid.nylon MSDS	H.MESH.ETH.0066036	H.MESH.ETH.0066078
09/??/10	Neuchatel - September 2010 Roles and Responsibilities	ETH.MESH.09932902	ETH.MESH.09932912
10/??/00	TVT Update Success & Complications - Bernard Jacquetin	ETH.MESH.04044797	ETH.MESH.04044800
10/??/03	Gynecare 7 Year Data Indicates Strong Continued Safety and Effectiveness for GYNECARE TVT Tension-free Support for Incontinence	ETH.MESH.05794787	ETH.MESH.05794788
10/??/08	IFPM position on FDA notification	ETH.MESH.17556582	ETH.MESH.17556582
10/??/2012	Clinical Data Review - 3 year data	ETH.MESH.07808480	ETH.MESH.07808481
10/26/2004, 1/4/2006	Email re: TVT Secur Publications	ETH.MESH.05537694	ETH.MESH.05537702
11/6/2006	Email re: TVT-S Complaint review	ETH.MESH.00329316	ETH.MESH.00329317
11/7/????	Dear Doctor Letter	ETH.MESH.00311769	
12/10/2005	Gynecare - Amendment 3 to design validation study Gynecare TVT Secur System	ETH.MESH.04385380	ETH.MESH.04335391
2/28/060	Email from David Robinson re tv t o training	ETH.MESH.846523	

DOCUMENTS

2/7/2007			
	Email re: Abstracts	ETH.MESH.01782942	ETH.MESH.01782962
2004/2005	Gynecare TVT Bio	ETH.MESH.06860553	ETH.MESH.06860558
2008?	ETHICON, INC. Worldwide Complaint - Reporting Statement	ETH.MESH.01130566	ETH.MESH.01130568
26/2007	Email re: Manuscript	ETH.MESH.01776968	ETH.MESH.01776984
3/31/2009	Communication Plan to close TVT WORLD Registry		
		ETH.MESH.03208952	ETH.MESH.03208955
5/7/????	TVT SECUR SYSTEM European Flying Surgeon Experience - Power Point	ETH.MESH.04112329	
5/9-11/2007	TVT SECUR - Recertification & Expert Meeting Agenda	ETH.MESH.03806230	
Jan-08			
	Summary of GYNECARE TVT SECUR Critical Steps	ETH.MESH.08585435	
N/A	Issue Report TVT Retropubic 2001 Open Date Between 01-Jan-2001 and 31-Dec-2001	ETH.MESH.02621559 at 02622276	
	Summary of 63 TVT-O RCTs - Batiste Defense Trial Exhibit	D23501.1	
	Mesh Weight Chart	Deposition Exhibit	
	Toglia presentation, The Mesh Story	ETH.MESH..16432550	ETH.MESH..16432550
	Annotated Prolift +M List of potential claims	ETH.MESH.00008631	ETH.MESH.00008631
	Letter of Proffer: Madigan Army Medical Center	ETH.MESH.00010743	ETH.MESH.00010743
	Prolift - Level One Mesh Course	ETH.MESH.00057142	ETH.MESH.00057146
	Franco Naples, FL Presentation - The Science of "What's Left Behind" . . .	ETH.MESH.00057515	ETH.MESH.00057531
	Voicemail from Kevin Mahar to EWH&U Sales & Marketing Organization re FDA PHN Product defect	ETH.MESH.00066960	ETH.MESH.00066960
	Presentation: Gynecare Prolift+M Pelvic Floor Repair System Training	ETH.MESH.00074499	ETH.MESH.00074499
	Feeney letter re Secondary Sales School #7	ETH.MESH.00140431	ETH.MESH.00140452
	Presentation draft - Tension-Free Support for Female SUI (258 Patients) - Modarelli, et al	ETH.MESH.00143842	ETH.MESH.00143842
	7 year Data Press Release - New Study Shows Minimally-Invasive Surgery for Female Incontinence Offers Good Long-Term Cure Rates	ETH.MESH.00155598	ETH.MESH.00155600
	Toth Memo w/ Gynecare TVT Professional Education Slides	ETH.MESH.00159634	ETH.MESH.00159719
	TVT Detail Sheet (TVTOO1R	ETH.MESH.00161444	ETH.MESH.00161445

DOCUMENTS

Final FDA Notification about Use of Surgical Mesh to Treat Pelvic Organ Prolapse and Stress Urinary Incontinence Standby for Media/Analyst inquiries	ETH.MESH.00164023	ETH.MESH.00164025
Mini TVT-O Team Meeting Agenda	ETH.MESH.00211038	ETH.MESH.00211041
Email Sandy Savidge to Donna Taggart re TVT EXACT IFU Proof Read 9/14/09	ETH.MESH.00211259	ETH.MESH.00211260
Email Susan Lin re TVT EXACT IFU Proof Read 9/14/09	ETH.MESH.00211263	ETH.MESH.00211265
DHF0000747 TVT Retropublic Refresh	ETH.MESH.00223634	ETH.MESH.00223655
Spreadsheet TVT Retropublic Refresh	ETH.MESH.00223640	ETH.MESH.00223640
Powerpoint TVT Retropublic Refresh	ETH.MESH.00223800	ETH.MESH.00223800
Design Input Strategy Project Mulberry by Dan Smith	ETH.MESH.00259269	ETH.MESH.00259274
Clinical Expert Report - Weisberg Assessment of the "inside-Out" Transobturator Approach to Implant . . .	ETH.MESH.00259634	ETH.MESH.00259644
Franco presentation - The Science of "What's Left Behind" . . . Evidence & Follow-Up of Mesh Use for SUI	ETH.MESH.00271641	ETH.MESH.00271641
Lamont email chain re !!!!Great News for TVT Laser Cut Mesh!!!!	ETH.MESH.00301741	ETH.MESH.00301742
TVT Laser Cut Mesh Project Revision History for DFMEA0000242	ETH.MESH.00301977	ETH.MESH.00301977
Maree, A email chain re AUSA update and telephone call with Prof Frazer	ETH.MESH.00311792	ETH.MESH.00311794
Presentation: Investigator Initiated Study Process by Kimberly Hunsicker, MSN, CRNP Regional Manager, Clinical Operations	ETH.MESH.00311832	ETH.MESH.00311848
Manley email chain re Project priorities for WH&U #1 TVT-Secur, #2 Laser cut TVT #3 Mint, #4 PROFIX	ETH.MESH.00321229	ETH.MESH.00321230
Definition for Major Invasive Surgeries and The Ethicon Franchise Products Requiring Major Invasive Procedures for Implantation	ETH.MESH.00321804	ETH.MESH.00321805
Yale email chain re TVT-S Update	ETH.MESH.00326882	ETH.MESH.00326884
Email Jennifer Paine to Catherine Beath, et al. re FDA Public Health Notice on Surgical Mesh for POP and SUI - URGENT	ETH.MESH.00329112	ETH.MESH.00329113
Lisa B email chain re TVT Patient Brochure Fair Balance EPI Changes	ETH.MESH.00339083	ETH.MESH.00339084
Spreadsheet DFMEA's TVT Classic	ETH.MESH.00340835	ETH.MESH.00340835
Hinoul P, Synopsis of preclinical data in support of TVT Abbrevio's equivalence to TVT-O	ETH.MESH.00346427	ETH.MESH.00346439
Spreadsheet TVT Secur dFMEA Rev #1	ETH.MESH.00349122	ETH.MESH.00349122
Abbrevio FAQs -	ETH.MESH.00350696	ETH.MESH.00350696
Annotated Slide	ETH.MESH.00353476	ETH.MESH.00353476
Spreadsheet DFMEA's re TVT-O pain	ETH.MESH.00354724	ETH.MESH.00354724
Spreadsheet DFMEA's re TVT-O pain	ETH.MESH.00354725	ETH.MESH.00354725

DOCUMENTS

	Differentiation Statement	ETH.MESH.00355435	ETH.MESH.00355435
	Review of Surgical Techniques Using Mesh, Robinson presentation	ETH.MESH.00396836	ETH.MESH.00396868
	Ulmsten letter to Rick	ETH.MESH.00400954	ETH.MESH.00400956
	Clinical Study Agreement between Dr. Douglas Grier and Ethicon	ETH.MESH.00401213	ETH.MESH.00401217
	Customer Initiated Research Grant Request (Wang)	ETH.MESH.00409659	ETH.MESH.00409663
	Letter from Martin Weisberg re 7 Year Data Indicates Strong Continued Safety and Effectiveness for Gynecare TVT Tension-free Support for Incontinence	ETH.MESH.00524444	ETH.MESH.00524445
	Product Quality Plan for Gynecare Gynemesh XL	ETH.MESH.00528636	ETH.MESH.00528641
	Annotated - Evaluation of the Fixation of TVT Abbrevio as compared to TVT-O in a Human Cadaveric Model	ETH.MESH.00576887	ETH.MESH.00576888
	Gynecare International Convention Recommendations	ETH.MESH.00581483	ETH.MESH.00581486
	Spreadsheet DFMEA's TVT Classic	ETH.MESH.00589494	ETH.MESH.00589494
	U.S. Launch Overview	ETH.MESH.00632655	ETH.MESH.00632655
	Gynecare TVT Sales Representative quick reference sheet	ETH.MESH.00640394	ETH.MESH.00640395
	Robinson email chain re TVT) versus TVT Secur efficacy and safety rates	ETH.MESH.00647404	ETH.MESH.00647409
	Mahar email chain re Continued Positive Feedback on LCM from EMEA - Rep Survey & Customer Guarantee attached	ETH.MESH.00708653	ETH.MESH.00708655
	Product Pointer	ETH.MESH.00746209E TH.MESH.00746209	ETH.MESH.00746209
	Surgeon Evaluation Questions for Laser Cut Mesh	ETH.MESH.00746210	ETH.MESH.00746212
	Spreadsheet DFMEA's TVT Classic	ETH.MESH.00748275	ETH.MESH.00748275
	K012628 TVT Blue System and Accessory TVT-AA	ETH.MESH.00748310	ETH.MESH.00748450
	abbrevio afmea rev a	ETH.MESH.00754439	ETH.MESH.00754446
	Email David Robinson to Giselle Bonet re forgot	ETH.MESH.00756984	ETH.MESH.00756984
	Memo to Jacqueline Russo from Ogilvy Public Relations	ETH.MESH.00766347	ETH.MESH.00766349
	Osman R email chain re 2008 Budget Spend	ETH.MESH.00772228	ETH.MESH.00772229
	Osman R email chain re Updated Fair Balance for TVT Brochure	ETH.MESH.00772231	ETH.MESH.00772232
	Email from David Robinson (Medical Director) re Risk/Benefit Analysis for TVT SECUR Clinical Expert Report	ETH.MESH.00823660	ETH.MESH.00823660
	Product Complaints Graph	ETH.MESH.00826046	ETH.MESH.00826047
	Smith D Memo re Gynecare Board risk discussion before launch	ETH.MESH.00858080	ETH.MESH.00858081
	London Brown Memo to Smith re Mechanical Cut vs Laser Cut Mesh Rationale	ETH.MESH.00858252	ETH.MESH.00858253
	Product Flowchart	ETH.MESH.00858891	ETH.MESH.00858891

DOCUMENTS

PT0-0746; Version 1 Validation Protocol for Knitting, Scouring and Heat-Setting 6-mil Old Construction Blue PROLENE Mesh at Secant Medical	ETH.MESH.00862227	ETH.MESH.00862235
MS729-XXX; Appendix 1	ETH.MESH.00862284	ETH.MESH.00862289
Email from Carolyn Brennan (Project Manager, Worldwide Customer Quality) re Updated TVT and TVT-O Complication Rates 11-15-05	ETH.MESH.00875647	ETH.MESH.00875649
Presentation: SUI, A Primary Care Perspective	ETH.MESH.00995657	ETH.MESH.00995657
Complaint Reporting Statement	ETH.MESH.00995835	ETH.MESH.00995836
Weisberg M Final Draft CER	ETH.MESH.00998286	ETH.MESH.00998291
TVT and TVT-O RMR Rev 1	ETH.MESH.01066916	ETH.MESH.01066932
Spreadsheet DFMEA's TVT Classic	ETH.MESH.01068862	ETH.MESH.01068862
Marketing Brochure - Make Data and Safety Your Choice	ETH.MESH.01186068	ETH.MESH.01186072
Hinoul - IUGA From presentation to publication: ensuring quality in the reporting of urogynaecology research	ETH.MESH.01186613	ETH.MESH.01186613
New STructures to create for GYNECARE TVT ABBREVO™ Anatomy Modules	ETH.MESH.01188589	ETH.MESH.01188613
Abbrevio Professional Education Presentation	ETH.MESH.01201957	ETH.MESH.01201957
Hinoul presentation: The future of surgical meshes: the industry's perspective	ETH.MESH.01203957	ETH.MESH.01203957
TVT-Abbrevio RMR Rev 1	ETH.MESH.01212090	ETH.MESH.01212099
Memo by Lynn Hall re Summary of Findings and Next Steps from 10.12.01 TVT DTC Focus Groups	ETH.MESH.01217285	ETH.MESH.01217288
Revision History for dFMEA0000242	ETH.MESH.01218019	ETH.MESH.01218019
TVT Laser Cut Mesh Rev 1	ETH.MESH.01218099	ETH.MESH.01218103
An independent biomechanical evaluation of commercially available suburethral slings Article	ETH.MESH.01221055	ETH.MESH.01221058
Dr. Letter	ETH.MESH.01226446	ETH.MESH.01226449
Spreadsheet DFMEA's TVT Classic	ETH.MESH.01247379	ETH.MESH.01247379
Spreadsheet DFMEA's TVT Classic	ETH.MESH.01250926	ETH.MESH.01250926
Spreadsheet DFMEA's TVT Classic	ETH.MESH.01250962	ETH.MESH.01250962
RMR TVT and TVT-O Rev 1	ETH.MESH.01265223	ETH.MESH.01265239
RMR for TVT and TVT-O Revision History for RMR-0000044	ETH.MESH.01268264	ETH.MESH.01268277
TVT Laser Cut RMR Rev 2	ETH.MESH.01310061	ETH.MESH.01310065
TVT RMR Rev 3	ETH.MESH.01310476	ETH.MESH.01310481
Spreadsheet DFMEA's TVT Classic	ETH.MESH.01310482	ETH.MESH.01310482
Spreadsheet DFMEA's TVT Classic	ETH.MESH.01419741	ETH.MESH.01419741
Test Method Validation Protocol: Visual Acceptance criteria for seal of Blister PVA-112940-TMV-PR	ETH.MESH.01592467	ETH.MESH.01592490
Test Method Validation Report: Visual Acceptance criteria for seal of Blister PVA-112940-TMV-RE Rev A	ETH.MESH.01592899	ETH.MESH.01592932

DOCUMENTS

Spreadsheet re Faculty, Preceptors, Speaking Training, etc.	ETH.MESH.01674264	ETH.MESH.01674264
Trzewik - Mesh design argumentation issues	ETH.MESH.01752532	ETH.MESH.01752535
TVT-Secur Quality Board presentation	ETH.MESH.01758770	ETH.MESH.01758801
Woods email chain re Trial	ETH.MESH.01760362	ETH.MESH.01760363
Robinson email chain re TVT-S Cookbooks	ETH.MESH.01784428	ETH.MESH.01784435
London-Brown A Memto to Parisi, Mahar re VOC on new Laser Cut TVT Mesh	ETH.MESH.01809082	ETH.MESH.01809083
Bell S email chain re VOC on Laser cut mesh	ETH.MESH.01811770	ETH.MESH.01811772
VOC Summary Mini Me - Presentation	ETH.MESH.01816436	ETH.MESH.01816436
Smith D email chain re TVT-Secur	ETH.MESH.01822361	ETH.MESH.01822363
Wurgeon Evaluatin Questions for Laser Cut Mesh	ETH.MESH.02106741	ETH.MESH.02106743
Physician Post-Operative Questionnaire	ETH.MESH.02106803	ETH.MESH.02106803
Division Meeting Notes: Continence Health	ETH.MESH.02108293	ETH.MESH.02108295
Memo to Rippy re Mechanisms of Cytotoxicity for TVT Polypropylene Mesh	ETH.MESH.02134271	ETH.MESH.02134273
Menneret D email chain re Mesh Fraying: Dr. Eberhard letter	ETH.MESH.02180826	ETH.MESH.02180827
Sibylle B Memo to Menneret D re TVT blue	ETH.MESH.02180828	ETH.MESH.02180830
Translation of PD Doctor Eberhard's letter	ETH.MESH.02180833	ETH.MESH.02180833
Completion Report, Design Verificaiton for Soft PROLENE Mesh/Mesh Curling	ETH.MESH.02182839	ETH.MESH.02182844
Presentation Script	ETH.MESH.02219162	ETH.MESH.02219164
Design Verification Protocol for TVT-O PAC [TOPA Clinical] Project 14495, Version 1 Study Number AST-2010-0536	ETH.MESH.02221369	ETH.MESH.02221378
Stability Study Protocol: SS# 1617 Project TVT-O Partially Absorbable (PA) - To Support Clinical Build	ETH.MESH.02221379	ETH.MESH.02221388
Patient Brochure - Stop coping. Start Living. Gynecare TVT Family of Products	ETH.MESH.02236580	ETH.MESH.02236595
Spanish Gynecare TVT patient brochure	ETH.MESH.02237665	ETH.MESH.02237696
New Product Introduction Presentation	ETH.MESH.02249435	ETH.MESH.02249435
Vellucci, L emal chain re Ethicon sponsored study	ETH.MESH.02252005	ETH.MESH.02252007
Spreadsheet DFMEA's TVT Classic	ETH.MESH.02265802	ETH.MESH.02265802
Spreadsheet DFMEA's TVT Classic	ETH.MESH.02265803	ETH.MESH.02265809
2009 Urology Advisory Board Meeting Somerville, NJ Agenda	ETH.MESH.02309289	ETH.MESH.02309290
Pompilio S email re Information about FDA notification on use of mesh in pelvic surgery	ETH.MESH.02310653	ETH.MESH.02310657
TVT IFU through	ETH.MESH.02340306	ETH.MESH.02340369
TVT IFU through	ETH.MESH.02340504	ETH.MESH.02340567
Prolene	ETH.MESH.02342102	ETH.MESH.02342102
TVT - Freedom From Stress Urinary Incontinence	ETH.MESH.02619504	ETH.MESH.02619511
TVT Classic 1999-2000 Issue Report	ETH.MESH.02620354	ETH.MESH.02621558

DOCUMENTS

Issue Report TVT Retropubic 1999-2000 Open Date Between 01-Jan-1999 and 31-Dec-2000	ETH.MESH.02620681	ETH.MESH.02620685
Issue Report TVT Retropubic 2001 Open Run Date Between 01-Jan-2001 and 31-Dec-2001	ETH.MESH.02621559	ETH.MESH.02622455
Issue Report TVT Retropubic 2001 Open Date Between 01-Jan-2001 and 31-Dec-2001	ETH.MESH.02621946	ETH.MESH.02621950
Issue Report TVT Retropubic 2001 Open Date Between 01-Jan-2001 and 31-Dec-2001	ETH.MESH.02621961	ETH.MESH.02621965
TVT Classic 2002	ETH.MESH.02623743	
TVT Classic 2003 Issue Report	ETH.MESH.02625055	ETH.MESH.02626377
TVT Retropubic 2003 Issue Report	ETH.MESH.02625060	ETH.MESH.02625064
Issue Report TVT Retropubic 2003 Open Date Between 01-Jan-2003 and 31-Dec-2003	ETH.MESH.02625065	ETH.MESH.02625069
Issue Report TVT Retropubic 2003 Open Date Between 01-Jan-2003 and 31-Dec-2003	ETH.MESH.02625419	ETH.MESH.02625423
Issue Report TVT Retropubic 2003 Open Date Between 01-Jan-2003 and 31-Dec-2003	ETH.MESH.02626097	ETH.MESH.02626101
TVT Classic 2005-2007 Issue Reports	ETH.MESH.02627331	ETH.MESH.02628697
TVT Classic 2008-2009 Issue Reports	ETH.MESH.02628698	ETH.MESH.02630133
TVT Classic 2010-2012 Issue Reports	ETH.MESH.02630134	ETH.MESH.02632004
Issue Report TVT-O 2005 Open Date Between 01-Jan-2005 and 31-Dec-2005	ETH.MESH.02653001	ETH.MESH.02653005
Issue Report TVT-O 2010 Open Date Between 01-Jan-2006 and 31-Dec-2006	ETH.MESH.02654027	ETH.MESH.02654034
Issue Report TVT-O 2010 Open Date Between 01-Jan-2010 and 31-Dec-2010	ETH.MESH.02656825	ETH.MESH.02656834
Robinson email chain re Pelvic Floor/Mesh Strategy	ETH.MESH.03160750	ETH.MESH.03160752
Run on eg log.txt	ETH.MESH.03334244	ETH.MESH.03334244
TVT IFU to present	ETH.MESH.03427878	ETH.MESH.03427946
Patient advertisement for TVT "One day you have urine leakage. The next day you don't. End of story."	ETH.MESH.03460640	ETH.MESH.03460640
Physician form letter re RVR51 - Gynecare TVT Secur System	ETH.MESH.03509755	ETH.MESH.03509755
Holloway ltr Ethicon France re fraying	ETH.MESH.03535750	ETH.MESH.03535750
Consulting Agreement between Dr. Brian Flynn and Ethicon	ETH.MESH.03605457	ETH.MESH.03605463
FM-0000167 Revision 4	ETH.MESH.03652925	ETH.MESH.03652956
510(k) Premarket Notification GYNECARE TVTO-PA Continence System	ETH.MESH.03654649	ETH.MESH.03654701
MS455-012; Revision 18 Material Specification for Pelletized Unpigmented	ETH.MESH.03671138	ETH.MESH.03671147
Email Martin Weisberg to Barbara McCabe re leVal	ETH.MESH.03715571	ETH.MESH.03715574
Check Liste D'Inspection Qualite - Final TVT-TVT-AA	ETH.MESH.03730703	ETH.MESH.03730722
Emails Martin Weisberg and Dr Peggy Norton re TVT	ETH.MESH.03738466	ETH.MESH.03738467
Table comparing meshes	ETH.MESH.03751168	ETH.MESH.03751168

DOCUMENTS

Gynecare Pro-lift Ad "Get the Facts, Be Informed, Make YOUR Best Decision"	ETH.MESH.03905968	ETH.MESH.03905975
Graft or No Graft - Arnaud presentation	ETH.MESH.03906527	ETH.MESH.03906527
Arnaud Memo "Confidential Trans-Obturator TVT-Procedure In-Out"	ETH.MESH.03907327	ETH.MESH.03907330
Emails Axel Arnud to Martin Weisberg re Soft Prolene	ETH.MESH.03910175	ETH.MESH.03910177
Arnaud email chain re Soft Prolene	ETH.MESH.03910183	ETH.MESH.03910185
Arnaud A email chain re Mini TVT - mesh adjustment	ETH.MESH.03910418	ETH.MESH.03910421
Bianchi R email chain re TVT event	ETH.MESH.03917309	ETH.MESH.03917312
Weisberg, M email re Mini TVT - mesh adjustment	ETH.MESH.03917375	ETH.MESH.03917378
Marketing Plan TOVT	ETH.MESH.03918352	ETH.MESH.03918352
2.0 Products in Development	ETH.MESH.03924530	ETH.MESH.03924539
History of TVT-O	ETH.MESH.03932909	ETH.MESH.03932911
The history of TVT	ETH.MESH.03932912	ETH.MESH.03932914
Presentation: "The Science of "What's Left Behind"... Evidence & Follow-Up of Mesh Use for SUI by Doug H. Grier, MD"	ETH.MESH.03965159	ETH.MESH.03965195
Presentation: TVTO Data 2006 & 2007 Ethicon Women's Health & Urology, The Netherlands	ETH.MESH.04049320	ETH.MESH.04049320
Marketing & Launch Plan	ETH.MESH.04061003	ETH.MESH.04061048
Grier Presentation - The Science of "What's Left Behing" . . . Evidence & Follow-Up of Mesh Use for SUI	ETH.MESH.04077109	ETH.MESH.04077145
Chen, Medical Assessment - . . . 68 issues from Germany	ETH.MESH.04081871	ETH.MESH.04081872
Study Notes, Meng Chen, PhD, Possible Complications for Surgeries to Correct Pelvic Organ Prolapse	ETH.MESH.04082973	ETH.MESH.04082974
Email Meng Chen to Carolyn Brennan re TVTs and bladder perforation	ETH.MESH.04090122	ETH.MESH.04090122
Email Meng Chen to Sergio Gadaleta, et al. re #10100080654 and TVT IFUs	ETH.MESH.04092868	ETH.MESH.04092869
Particles in TVTO Blisters presentation	ETH.MESH.04101824	ETH.MESH.04101824
Check Liste D'Inspection Qualite	ETH.MESH.04321393	ETH.MESH.04321396
Check Liste D'Inspection Qualite	ETH.MESH.04321397	ETH.MESH.04321400
Check Liste D'Inspection Qualite	ETH.MESH.04321401	ETH.MESH.04321404
Check Liste D'Inspection Qualite	ETH.MESH.04321405	ETH.MESH.04321408
Check Liste D-Inspection Qualite	ETH.MESH.04321409	ETH.MESH.04321412
Check Liste D'Inspection Qualite	ETH.MESH.04321413	ETH.MESH.04321417
Check Liste D'Inspection Qualite	ETH.MESH.04321418	ETH.MESH.04321435
Check Liste D'Inspection Qualite	ETH.MESH.04321436	ETH.MESH.04321453
Check Liste D-Inspection Qualite	ETH.MESH.04321454	ETH.MESH.04321471
Check Liste D'Inspection Qualite	ETH.MESH.04321472	ETH.MESH.04321487
Check Liste D'Inspection Qualite	ETH.MESH.04321488	ETH.MESH.04321503

DOCUMENTS

Visual Acceptance Criteria for Blister Sealing; VSE0007, Revision: E	ETH.MESH.04321682	ETH.MESH.04321693
Visual Acceptance Criteria for Blister Sealing; VSE0007, Revision: F	ETH.MESH.04321694	ETH.MESH.04321705
Visual Acceptance Criteria for Blister Sealing; VSE0007, Revision: G	ETH.MESH.04321706	ETH.MESH.04321717
File - TVT vs Colposuspension for GS1	ETH.MESH.04448285	ETH.MESH.04448323
Holste presentation: Lightweight Mesh Developments	ETH.MESH.04941016	ETH.MESH.04941049
Commonly Asked Questions and Objections script	ETH.MESH.05119622	ETH.MESH.05119631
Mesh vs Non-Mesh Pending PR/Regulatory Issues	ETH.MESH.05120364	ETH.MESH.05120365
Email Linda Linton re TVT 11 Year E-blast Results (1st Round)	ETH.MESH.05183409	ETH.MESH.05183410
Mesh vs Non-Mesh Pending PR/Regulatory Issues	ETH.MESH.05210364	ETH.MESH.05210365
Division flowcharts	ETH.MESH.05217971	ETH.MESH.05217976
TVT Patent Portfolio - Slater-Tomko presentation	ETH.MESH.05236223	ETH.MESH.05236255
Trzewik memo re Mesh design argumentation issues	ETH.MESH.05237034	ETH.MESH.05237037
LIGHTning Project Charter - Meier et al presentation	ETH.MESH.05237336	ETH.MESH.05237382
Article on pp change in sheep model	ETH.MESH.05240144	ETH.MESH.05240144
LIGHTning Project Charter Presentation	ETH.MESH.05352721	ETH.MESH.05352766
MSE0181; Revision A Pilot Neuchatal Material Specification SCION Right and Left inserter assembly	ETH.MESH.05367673	ETH.MESH.05367679
Selecting the Right Mesh - Professional Education presentation	ETH.MESH.05403236	ETH.MESH.05403236
Applied Science & Technology Performance Evaluation Abstract Biaxial testing of two commonly used Ethicon meshes	ETH.MESH.05442973	ETH.MESH.05442975
Seven Year Data for Ten Year Prolene Study	ETH.MESH.05453719	ETH.MESH.05453727
The (clinical) argument of lightweight mesh in abdominal surgery Presentation	ETH.MESH.05479411	ETH.MESH.05479411
Mesh porosity chart	ETH.MESH.05479535	ETH.MESH.05479535
Raw material specification - TVT Secur * System (semi finished good from Neuchatel, Switzerland)	ETH.MESH.05500891	ETH.MESH.05500901
Materials - defect spreadsheet	ETH.MESH.05514963	ETH.MESH.05514963
Smith D email chain re TVT-S Cookbooks	ETH.MESH.05519476	ETH.MESH.05519481
Hoepffner, H email re Problem Statements for TVT Brainstorming Meeting	ETH.MESH.05529653	ETH.MESH.05529653
Emails Patricia Hojnoski and Martin Weisberg et al. re: Updated TVT and TVT-O Complication Rates 11-15-05	ETH.MESH.05560961	ETH.MESH.05560963
PVP OQ for Foil Pouches	ETH.MESH.05639356	ETH.MESH.05639361
TVT STAF PD 99/20 -- Meeting of Nov. 17, 1999 Summary	ETH.MESH.05641096	ETH.MESH.05641098
Pelvic Floor Repair -- Surgeon's Feed-back on Mesh Concept	ETH.MESH.05644163	ETH.MESH.05644171
Babcock presentation	ETH.MESH.05806931	ETH.MESH.05806931

DOCUMENTS

	Chronic Pain Prevention/future - Bioengineer's point of view Presentation	ETH.MESH.05916450	ETH.MESH.05916450
	Presentation: Solving the Device Design Puzzle	ETH.MESH.05918082	ETH.MESH.05918116
	Asset Purchase Agreement	ETH.MESH.05972834	ETH.MESH.05972866
	Consulting Agreement between Dr. Douglas Grier and Ethicon	ETH.MESH.05973195	ETH.MESH.05973200
	Savidge email chain re Mesh and Biomechanical Data for TVTO-PA 510(k)	ETH.MESH.06015836	ETH.MESH.06015839
	TVT-444-10-11/12 Patient brochure - stop coping. start living. As yourself . . . Are you suffering from any of these symptoms?	ETH.MESH.06087471	ETH.MESH.06087472
	Spreadsheet	ETH.MESH.06171801	ETH.MESH.06171801
	Divilio memo	ETH.MESH.06195201	ETH.MESH.06195205
	Dodd presentation: TVT: Insights into the Making of a Revolution	ETH.MESH.06859904	ETH.MESH.06859931
	Gynecare TVT-S Competitive Product Update	ETH.MESH.06861473	ETH.MESH.06861473
	Kammerer email re Ultra sonic slit TVT	ETH.MESH.06866919	ETH.MESH.06866919
	ETH.MESH.06866921 attachment	ETH.MESH.06866921	ETH.MESH.06866921
	Presentation - Scion PP	ETH.MESH.06921531	ETH.MESH.06921531
	Memo Evaluation of the Mesh Elongation, Function of Number of Wales	ETH.MESH.06926711	ETH.MESH.06926714
	FDA Communication re PS120095 GYNECARE TVT Secur System	ETH.MESH.07218087	ETH.MESH.07218088
	Biocompatibility Risk Assessment: PROSIMA Pelvic Floor Repair System (Mint)	ETH.MESH.07506983	ETH.MESH.07506985
	Presentation: Sicon PA Commercial Strategy	ETH.MESH.07903520	ETH.MESH.07903520
	FDA Public Health Notification: Serious Complications Associated with Transvaginal Placement of Surgical Mesh in Repair of POP and SUI	ETH.MESH.07937826	ETH.MESH.07937828
	TVVT016R9 Patient brochure - stop coping. start living	ETH.MESH.08003279	ETH.MESH.08003294
	Presentation TVT Abbrevio Incontinence System Professional Education by Dr. Grier	ETH.MESH.08004035	ETH.MESH.08004035
	Grier Consulting Agreement Requisition Form	ETH.MESH.08007502	ETH.MESH.08007512
	Hurricane and The Stars Divisional Meeting Orlando Marriott World Center Agenda	ETH.MESH.08050183	ETH.MESH.08050183
	Emails Dr. Brigitte Hellhammer to Dr. Hans-Jochen Hoepffner, et al. re Cardozo Trial	ETH.MESH.08167644	ETH.MESH.08167645
	LCM Project: Photographs Comparing Laser Cut Mesh vs Mechanical Cut Mesh	ETH.MESH.08334245	ETH.MESH.08334245
	Mahar email chain re Contact at Lifescan who ran the BB King campaign	ETH.MESH.08345895	ETH.MESH.08345895
	TVT Obturator System Product Description	ETH.MESH.08376560	ETH.MESH.08376564
	Toglia Presentation - The Mesh Story working copy	ETH.MESH.08426862	ETH.MESH.08426867
	Cecchini TVT package insert comments	ETH.MESH.08505071	ETH.MESH.08505071

DOCUMENTS

Medhekar email chain re Ethicon Mesh DVD - FDA Request Follow-Up	ETH.MESH.08516130	ETH.MESH.08516132
Zaddem email re cannulae metal particles	ETH.MESH.08561511	ETH.MESH.08561511
Kirkemo ltr to Dr. Kondrup re request for information	ETH.MESH.08570968	ETH.MESH.08570970
Equivalence Supported by Pre-clinical Performance Studies	ETH.MESH.08581280	ETH.MESH.08581282
Literature on TVT-O sling and pain management	ETH.MESH.08584142	ETH.MESH.08584143
Franchise Procedure for Controlling Substances of Concern Revision History PR-0000558	ETH.MESH.08664680	ETH.MESH.08664686
Cancellation Agreement between Ethicon, Inc., Contape S.A., and the estate of Professor Ulf Ivar Ulmsten	ETH.MESH.08692670	ETH.MESH.08692672
Consulting Agreement between Ethicon, Inc. and Contape S.A. and Professor Ulf Ivar Ulmsten	ETH.MESH.08692673	ETH.MESH.08692696
Medscand Agreement Files	ETH.MESH.08696085	ETH.MESH.08696134
Instruction Standard TVT EXACT product Plan and Rationald Appendix I, Revision A	ETH.MESH.08776231	ETH.MESH.08776238
Nonnenmann Performance Evaluation - Memo re TVT+M Mesh Tensile Strength	ETH.MESH.08776793	ETH.MESH.08776794
RMR - LCM Revision 2	ETH.MESH.08792102	ETH.MESH.08792106
Cario email chain re Dr. Wang's proposal	ETH.MESH.08793207	ETH.MESH.08793210
Ailawadi - Does Material Matter - final	ETH.MESH.08968369	ETH.MESH.08968378
Elongation test data	ETH.MESH.09004554	ETH.MESH.09004554
Elongation test data - delayed launch	ETH.MESH.09004555	ETH.MESH.09004555
Savidge S email chain re 510k Mint tests pending	ETH.MESH.09052531	ETH.MESH.09052534
Operation Abbrevio Combat Training Splash Storyboard	ETH.MESH.09170211	ETH.MESH.09170213
Toglia The Mesh Story PPT	ETH.MESH.09214439	ETH.MESH.09214443
Rousseau R Memo re Meeting Minutes of Project Planning Meeting	ETH.MESH.09264884	ETH.MESH.09264885
Memo to Rousseau re Biocomp Risk Assess Prolene	ETH.MESH.09279161	ETH.MESH.09279161
Notes re customers frustration with Ethicon rep	ETH.MESH.09293114	ETH.MESH.09293114
Email from Jurgen Trzewik and attachment	ETH.MESH.09656790	
Email from Jurgen Trzewik and attachment	ETH.MESH.09656792	
Engel email chain re Gynemesh PS w/Monocryl	ETH.MESH.09664947	ETH.MESH.09664950
Material specification spreadsheet	ETH.MESH.09671620	ETH.MESH.09671620
Stop Coping. Start Living. What you should know about stress urinary incontinence. Brochure	ETH.MESH.09744858	ETH.MESH.09744863
Barabas Memo re Operations Due Diligence - TVT/Tome	ETH.MESH.09748041	ETH.MESH.09748044
Consultancy Agreement	ETH.MESH.09748842	ETH.MESH.09748846
Consultancy Agreement	ETH.MESH.09748848	ETH.MESH.09748853
Seven Year Data for Ten Year Prolene Study	ETH.MESH.09888187	ETH.MESH.09888223
ETH.MESH.09905181 Abbrevio Lessons Learned - Preliminary Report Out	ETH.MESH.09905181	ETH.MESH.09905181

DOCUMENTS

Survey Results	ETH.MESH.09905193	ETH.MESH.09905193
Abbrevio Lessons Learend - Summary Report out	ETH.MESH.09909020	ETH.MESH.09909025
Elbert Memo to TVTO PA (TOPA) DHF0000978 re R&D Memorandum on PA Mesh Assessments for TVTO-PA	ETH.MESH.09922570	ETH.MESH.09922578
510(k) Premarket Notification GYNECARE TVTO-OA Continence System	ETH.MESH.09984519	ETH.MESH.09984576
Abbrevio Lessons Learned Pre-Survey Results	ETH.MESH.09985777	ETH.MESH.09985777
Ulmsten - Anesthesiological routines for the TVT Procedure	ETH.MESH.10181793	ETH.MESH.10181797
TVT Update Report on Proposed Changes	ETH.MESH.10182456	ETH.MESH.10182461
1998 Gynecare European Marketing Plan	ETH.MESH.10183005	ETH.MESH.10183061
An Evaluation of the application of the GYNECARE TVT Obturator System Tension-free Support for Incontinence with Laser Cut Mesh Protocol	ETH.MESH.10372554	
Email Christopher Teasdale to Brian Luscombe re FW: Design Validation Surgeons with partial attachment	ETH.MESH.10525611	ETH.MESH.10525612
TVT Improvement Project Conference Call	ETH.MESH.10591803	ETH.MESH.10591804
TVT and TVT-O Rev. 1	ETH.MESH.1066916	ETH.MESH.1066932
Boston Scientific Slings presentation	ETH.MESH.10958575	ETH.MESH.10958586
Grier attached to TVT Exact deal	ETH.MESH.11175843	ETH.MESH.11175843
TVT Exact Tseng data	ETH.MESH.11175844	ETH.MESH.11175844
Be confident in the mesh you leave behind with Gynecare TVT Abbrevio	ETH.MESH.11175863	ETH.MESH.11175863
TVT Exact selling guide slide 9 and 11	ETH.MESH.11175864	ETH.MESH.11175864
Risk Assessment Summary for Products in the Gynecare TVT Secure System	ETH.MESH.11353422	
Piet Hinoul, MD - IUGA From presentation to publication: ensuring qualify in the reporting of urogynaecology research	ETH.MESH.1186613	
TVT Family of Products Sales Rep Promotion TVT Fast Break	ETH.MESH.11917445	ETH.MESH.11917450
TVT Improvement Project conference call notes	ETH.MESH.12009079	ETH.MESH.12009081
TVT Abbrevio Rev. 1	ETH.MESH.1212090	ETH.MESH.1212099
TVT LCM Project Revision History for dFMEA0000242, TVT Laser Cut Mesh Project	ETH.MESH.1218019	
TVT Laser Cut Mesh Rev. 1	ETH.MESH.1218099	ETH.MESH.1218103
TVT and TVT-O Rev. 2	ETH.MESH.1268264	ETH.MESH.1268277
RFI Instructions	ETH.MESH.12877118	ETH.MESH.12877118
Spreadsheet Revision History - Defect to Harms Map	ETH.MESH.12907175	ETH.MESH.12907175
1998 U.S. Marketing Research Study on TVT	ETH.MESH.130934	ETH.MESH.130941
TVT Laser Cut Mesh Rev. 2	ETH.MESH.1310061	ETH.MESH.1310065
TVT Laser Cut Mesh Rev. 3	ETH.MESH.1310476	ETH.MESH.1310481
Kyle Itt Chen re Customer's experience with TVT-O	ETH.MESH.13226457	ETH.MESH.13226457
RFI Instructions	ETH.MESH.13374559	ETH.MESH.13374559

DOCUMENTS

	Draft Template: DRM for Device Functionality (Performance & Safety)	ETH.MESH.13376661	ETH.MESH.13376868
	Vailhe email chain re Pore Size of Gynemesh PS and TVT Tapes	ETH.MESH.13523693	ETH.MESH.13523696
	Check Liste D'Inspection Qualite	ETH.MESH.13797826	ETH.MESH.13797830
	Secant Knitting Mesh Evaluation Revision A	ETH.MESH.13825635	ETH.MESH.13825639
	Validation strategy for TVT retropubic refresh (TVT RR) manufacturing process at Neuchatel	ETH.MESH.13840459	ETH.MESH.13840466
	Check Liste D'Inspection Qualite	ETH.MESH.13860322	ETH.MESH.13860342
	Check Liste D'Inspection Qualite Final TVT/TVT-AA	ETH.MESH.13869615	ETH.MESH.13869634
	Spreadsheet	ETH.MESH.14221357	ETH.MESH.14221357
	Work Instructions for In-Process & Finished Goods Defect Classifications for Ethicon Products, Appendix 1 - Assembly Errors	ETH.MESH.14450971	ETH.MESH.14451103
	Work Instructions for In-Process & Finished Goods Defect Classifications for Ethicon Products, Appendix 8 - Mesh	ETH.MESH.14451057	ETH.MESH.14451059
	Primary Blister Defect Definitions and Classifications RElease Level: 4 Production	ETH.MESH.14451060	ETH.MESH.14451068
	Spreadsheet	ETH.MESH.14471186	ETH.MESH.14471186
	Millicker email chain re addtl info - TVT & Prosima	ETH.MESH.14852589	ETH.MESH.14852590
	Complaint PI1E8VOWN	ETH.MESH.14901753	ETH.MESH.14901753
	Millicker email chain re Addtl Info TVT & Prosima	ETH.MESH.14901754	ETH.MESH.14901755
	CAPA130022 - Summary Report - particles	ETH.MESH.15137969	ETH.MESH.15137978
	CAOA 130022 - Failure Investigation - particles	ETH.MESH.15137980	ETH.MESH.15137983
	ETHICON - Rules for Laboratory Notebooks	ETH.MESH.15144988	ETH.MESH.15145028
	Smith email chain re Pore Size of Gynemesh PS and TVT Tapes	ETH.MESH.15362144	ETH.MESH.15362147
	Guidoin Lab Notebook Page/Image	ETH.MESH.15406846	ETH.MESH.15406856
	Guidoin Lab Notebook Page/Image	ETH.MESH.15406857	ETH.MESH.15406859
	Guidoin Lab Notebook Page/Image	ETH.MESH.15406860	ETH.MESH.15406861
	Guidoin Lab Notebook Page/Image	ETH.MESH.15406862	ETH.MESH.15406863
	Guidoin Lab Notebook Page/Image	ETH.MESH.15406864	ETH.MESH.15406866
	Guidoin Lab Notebook Page/Image	ETH.MESH.15406867	ETH.MESH.15406868
	Guidoin Lab Notebook Page/Image	ETH.MESH.15406869	ETH.MESH.15406870
	Guidoin Lab Notebook Page/Image	ETH.MESH.15406871	ETH.MESH.15406873
	Guidoin Lab Notebook Page/Image	ETH.MESH.15406874	ETH.MESH.15406876
	Guidoin Lab Notebook Page/Image	ETH.MESH.15406877	ETH.MESH.15406879
	Guidoin Lab Notebook Page/Image	ETH.MESH.15406880	ETH.MESH.15406881
	Guidoin Lab Notebook Page/Image	ETH.MESH.15406882	ETH.MESH.15406883
	Guidoin Lab Notebook Page/Image	ETH.MESH.15406884	ETH.MESH.15406885
	Guidoin Lab Notebook Page/Image	ETH.MESH.15406886	ETH.MESH.15406887
	Guidoin Lab Notebook Page/Image	ETH.MESH.15406888	ETH.MESH.15406889
	Guidoin Lab Notebook Page/Image	ETH.MESH.15406890	ETH.MESH.15406892
	Guidoin Lab Notebook Page/Image	ETH.MESH.15406893	ETH.MESH.15406894

DOCUMENTS

Guidoin Lab Notebook Page/Image	ETH.MESH.15406895	ETH.MESH.15406896
Guidoin Lab Notebook Page/Image	ETH.MESH.15406897	ETH.MESH.15406899
Guidoin Lab Notebook Page/Image	ETH.MESH.15406900	ETH.MESH.15406902
Guidoin Lab Notebook Page/Image	ETH.MESH.15406903	ETH.MESH.15406905
Guidoin Lab Notebook Page/Image	ETH.MESH.15406906	ETH.MESH.15406909
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Guidoin Lab Notebook Page/Image	ETH.MESH.15406927	ETH.MESH.15406928
Guidoin Lab Notebook Page/Image	ETH.MESH.15406929	ETH.MESH.15406930
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Guidoin Lab Notebook Page/Image	ETH.MESH.15406948	ETH.MESH.15406949
Guidoin Lab Notebook Page/Image	ETH.MESH.15406950	ETH.MESH.15406951
Guidoin Lab Notebook Page/Image	ETH.MESH.15406952	ETH.MESH.15406953
Guidoin Lab Notebook Page/Image	ETH.MESH.15406954	ETH.MESH.15406955
Guidoin Lab Notebook Page/Image	ETH.MESH.15406956	ETH.MESH.15406957
Guidoin Lab Notebook Page/Image	ETH.MESH.15406958	ETH.MESH.15406960
Guidoin Lab Notebook Page/Image	ETH.MESH.15406961	ETH.MESH.15406962
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Guidoin Lab Notebook Page/Image	ETH.MESH.15406965	ETH.MESH.15406966
Guidoin Lab Notebook Page/Image	ETH.MESH.15406967	ETH.MESH.15406968
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Guidoin Lab Notebook Page/Image	ETH.MESH.15406973	ETH.MESH.15406973
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Guidoin Lab Notebook Page/Image	ETH.MESH.15406979	ETH.MESH.15406981
Guidoin Lab Notebook Page/Image	ETH.MESH.15406982	ETH.MESH.15406984
Guidoin Lab Notebook Page/Image	ETH.MESH.15406985	ETH.MESH.15406986
Guidoin Lab Notebook Page/Image	ETH.MESH.15406987	ETH.MESH.15406988
Guidoin Lab Notebook Page/Image	ETH.MESH.15406989	ETH.MESH.15406989

DOCUMENTS

	Guidoin Lab Notebook Page/Image	ETH.MESH.15406990	ETH.MESH.15406991
	Guidoin Lab Notebook Page/Image	ETH.MESH.15406992	ETH.MESH.15406993
	Guidoin Lab Notebook Page/Image	ETH.MESH.15406994	ETH.MESH.15406997
	Guidoin Lab Notebook Page/Image	ETH.MESH.15406998	ETH.MESH.15406999
	Email Lissette Caro-Rosado to Ronald Horton, et al. RE: KOL Usage	ETH.MESH.15426052	ETH.MESH.15426053
	Clinical Strategy Project Scion PP & Scion PA - annotated	ETH.MESH.15928408	ETH.MESH.15928411
	Guidoin Lab Notebook Page/Image	ETH.MESH.15958336	ETH.MESH.15958395
	Guidoin Lab Notebook Page/Image	ETH.MESH.15958470	ETH.MESH.15958477
	Guidoin Lab Notebook Page/Image	ETH.MESH.15958478	ETH.MESH.15958480
	Guidoin Lab Notebook Page/Image	ETH.MESH.15958481	ETH.MESH.15958485
	Guidoin Lab Notebook Page/Image	ETH.MESH.15958486	ETH.MESH.15958491
	Guidoin Lab Notebook Page/Image	ETH.MESH.15958492	ETH.MESH.15958494
	Guidoin Lab Notebook Page/Image	ETH.MESH.15958495	ETH.MESH.15958502
	Guidoin Lab Notebook Page/Image	ETH.MESH.15958503	ETH.MESH.15958507
	Guidoin Lab Notebook Page/Image	ETH.MESH.15958508	ETH.MESH.15958509
	Guidoin Lab Notebook Page/Image	ETH.MESH.15958510	ETH.MESH.15958511
	Guidoin Lab Notebook Page/Image	ETH.MESH.15958512	ETH.MESH.15958517
	Guidoin Lab Notebook Page/Image	ETH.MESH.15958518	ETH.MESH.15958523
	2001 Gynecare TVT Professional Education Enhancements	ETH.MESH.159634	ETH.MESH.159719
	Consulting Agreement between Dr. Douglas Grier and Ethicon	ETH.MESH.16260624	ETH.MESH.16260629
		ETH.MESH.163583	
	Dr. Ramashandha Hosmane ltr	ETH.MESH.16359413	ETH.MESH.16359416
	Toglia presentation, The Mesh Story	ETH.MESH.16432550	ETH.MESH.16432550
	Jurgen Trzewik Memo re Mesh design argumentation issues	ETH.MESH.1752532	
	Physician Consultation Visit Regarding Decision for Surgery Form	ETH.MESH.17556583	ETH.MESH.17556583
	Complete Mulberry R&D Team and Launch team Webcast - Accomplishments/Individual team recognition	ETH.MESH.17789897	ETH.MESH.17789898
		ETH.MESH.2019485	
	Sunoco PP MSDS	ETH.MESH.2026591	ETH.MESH.2026595
	Carol Gillick 3/30/1999 Email RE: TVT Insert	ETH.MESH.203456	
	Physician Post-Operative Questionnaire	ETH.MESH.2106803	
	Revision Hx for pFMEA-0000497	ETH.MESH.21488624	ETH.MESH.21488636
	DHF1019 TVT-O	ETH.MESH.222779	ETH.MESH.223267
	Abbrevio marketing video	ETH.MESH.2229061	
	DHF0000747 TVT Retropublic Refresh	ETH.MESH.223634	ETH.MESH.223655
	Jacobs email chain re TVT Defect to Harm Map	ETH.MESH.22680210	ETH.MESH.22680216

DOCUMENTS

	TVT-12/22/2003 through 02/21/2005	ETH.MESH.2340306	ETH.MESH.2340369
	TVT 02/11/2005 through 04/07/2006	ETH.MESH.2340471	ETH.MESH.2340503
	TVT 10/13/2008 through 11/22/2010	ETH.MESH.2340504	ETH.MESH.2340567
	TVT-O IFU	ETH.MESH.2340829	
	Gynecare TVT Obturator System IFU	ETH.MESH.2340902	
	Prolene	ETH.MESH.2342102	
	TVT Classic 1999-2000	ETH.MESH.2620354	ETH.MESH.2621558
	TVT Classic 2003	ETH.MESH.2625055	ETH.MESH.2626377
	TVT Classic 2005-2007	ETH.MESH.2627331	ETH.MESH.2628697
	TVT Classic 2008-2009	ETH.MESH.2628698	ETH.MESH.2630133
	TVT Classic 2010-2012	ETH.MESH.2630134	ETH.MESH.2632004
	Nick Franco, MD Naples, FL presentation: The Science of "What's Left Behing"... Evidence & Follow-Up of Mesh Use for SUI	ETH.MESH.271641	
	TVT Laser Cut Mesh Project Revision History for DFMEA0000242	ETH.MESH.301977	
	TVT Classic	ETH.MESH.340835	
	TVT 11/29/2010 to present	ETH.MESH.3427878	ETH.MESH.3427946
	TVT Secur dFMEA Rev #1	ETH.MESH.349122	
	MS455-012; Revision 18 Material Specification for Pelletized Unpigmented Polypropylene Resin (Type F040-S Undyed)	ETH.MESH.3671138	ETH.MESH.3671147
		ETH.MESH.371551	
		ETH.MESH.3738468	
	Ex. T-502	ETH.MESH.3918253	
	The history of TVT	ETH.MESH.3932912	ETH.MESH.3932914
	Ex. T-499	ETH.MESH.3934952	
		ETH.MESH.3965159	
	Ulmsten letter to Rick	ETH.MESH.400954	ETH.MESH.400956
		ETH.MESH.4049320	
	Study Notes, Meng Chen MD, PhD, Possible Complications for Surgeries to Correct Pelvic Organ Prolapse and Stress Urinary Incontinence	ETH.MESH.4082973	
	Printout from 1998 Guidoin Explant	ETH.MESH.4755	
	Dr. Jorge Holste Presentation: Lightweight Mesh Developments	ETH.MESH.4941016	
		ETH.MESH.5119622	
	TVT 04/07/2006 through 10/07/2008	ETH.MESH.5222673	ETH.MESH.5222705
	TVT 01/16/2010 through (unavailable)	ETH.MESH.5225354	ETH.MESH.5225385
	Trzewik, J, Ethicon R&D, Mesh design argumentation issues	ETH.MESH.5237034	ETH.MESH.5237037
	Product Quality Plan for Gynecare Gynemesh XL Revision History for (PQP-000000)	ETH.MESH.528636	ETH.MESH.528641

DOCUMENTS

MSE0181; Revision A ** Pilot** Neuchatel Material Specification SCION; Right and left inserter assembly	ETH.MESH.5367673	ETH.MESH.5367679
Hellhammer email to Dr. Hoefer 6/1/2001	ETH.MESH.5494064	ETH.MESH.5494066
Norderstedt RMS-001001 4E; Revision 5 Neuchatel TVT-S raw material specification semi-finished products from Sarl	ETH.MESH.5500891	ETH.MESH.5500901
Product Excel Spreadsheet	ETH.MESH.5514963	
TVT Secur Rev. 1	ETH.MESH.5534009	ETH.MESH.5534013
Pelvic Floor Repair-Surgeon's Feed-back on Mesh Concept	ETH.MESH.5644163	ETH.MESH.5644171
	ETH.MESH.5795299	
	ETH.MESH.5795322	
Solving the Device Design Puzzle description of Secant medical	ETH.MESH.5918082	ETH.MESH.5918116
EOC131; Revision A Neuchatel Prolift+M product specification	ETH.MESH.6214296	ETH.MESH.6214300
	ETH.MESH.640394	
Patient brochure	ETH.MESH.658454	
	ETH.MESH.6880021	
Ex. T-522	ETH.MESH.6880472	
	ETH.MESH.6884249	
Gynecare Pro-Lift+M Pelvic Floor Repair System Training Presentation	ETH.MESH.74499	
LCM Product Pointer	ETH.MESH.746209	
Surgeon Evaluation Questions for Laser Cut Mesh	ETH.MESH.746210	
Email from Dr. Dennis Miller to Dharini Amin	ETH.MESH.756887	
Email from David Robinson, MD to Giselle Bonet and Marty Weisberg	ETH.MESH.756984	
	ETH.MESH.8003263	
	ETH.MESH.8003264	
	ETH.MESH.8003291	
	ETH.MESH.8167644	
LCM Project: Photographs Comparing Laser Cut Mesh vs Mechanical Cut Mesh	ETH.MESH.8334245	
	ETH.MESH.8376560	
Peter Cecchini TVT package insert comments	ETH.MESH.8505071	
Brian Luscombe Slides: Top Ten Reasons to Pursue Gynecare TVT Obturator System	ETH.MESH.857821	
LIMS Project #: BE-2004-916 Secant from Cornelia 2004 Validation	ETH.MESH.862206	ETH.MESH.862208
PT0-0746; Version 1 Validation Protocol for Knitting, Scouring and Heat-Setting 6-mil Old Construction Blue PROLENE Mesh at Secant Medical	ETH.MESH.862227	862235

DOCUMENTS

MS729-XXX; Appendix I Neuchatel Material Specification for TVT Prolene* Polypropylene Mesh Roll Stock	ETH.MESH.862284	ETH.MESH.862289
Email Brian Luscombe to Dan Smith and Janice Burns, et al.	ETH.MESH.864085	ETH.MESH.864086
TVT-O IFU	ETH.MESH.864131	
	ETH.MESH.8696091	
	ETH.MESH.8696116	
	ETH.MESH.8696132	
Elongation test data	ETH.MESH.9004550	
Abbrevio marketing video - script	ETH.MESH.9170211	
	ETH.MESH.9656795	
Chart re Prolene weight and pore size	ETH.MESH.9671620	
History of mesh production and processing	ETH-03877	ETH-03886
History of mesh production and processing 08 Stability Completion Report	ETH-3877	ETH-3886
Slide: Selecting the Right Mesh	ETH-50330	
Check Liste D'Inspection Qualite	ETH-53294	ETH-53294
Chevron Materials Safety Data Sheet Marlex Polypropylenes (All Grades) Revision Number: 3	Ex. T-3137	
Data Review - 120 day results for Scion (TVT+M) Ingrowth Study PSE 10-0126	HMESH_ETH_0204160 3	HMESH_ETH_0204160 3
Marrero email re PPQ Protocol from 5 mil construction	HMESH_ETH_0251252 1	HMESH_ETH_0251252 1
Stockholm Trip Report	HMESH_ETH_0278170 7	HMESH_ETH_0278170 8
Reprint: ULTRAPRO Hernia System: Toward and ideal solution: The Bonheiden experience with a partially absorbable and macroporous bilayer device	HMESH_ETH_0325764 8	HMESH_ETH_0325765 5
Text File	HMESH_ETH_0650981 6	HMESH_ETH_0650981 6
Draft AUGS-SUFU Position Statement on Mesh Midurethral Slings for Stress Urinary Incontinence	MIL000268	MIL000274
Draft - AUGS-SUFU Position Statement on Mesh Midurethral Slings for Stress Urinary Incontinence	MIL00268	
AUGS/SUFU MUS Task Force Agenda	MIL00282	
Training Videos	PM.000003.m4v	
Training Videos - Retropubic Implantation Video	PM.000004.m4v	
Training Videos	PM.000011.m4v	
Training Videos	PM.00003.m4v	PM.00003.m4v
Training Videos - Retropubic Implantation Video	PM.00004.m4v	PM.00004.m4v
Training Videos	PM.00011.m4v	PM.00011.m4v
Material Safety Data Sheet, Chevron Philips 2004	T-3137	T-3137
Email re: Clinical Strategy for SECUR	ETH.MESH.03172197	ETH.MESH.03172198

DOCUMENTS

	TVT-Secur Quality Board Power Point	ETH.MESH.00874445	
	Gynecare TVT Secur System Tension-free Support for Incc	ETH.MESH.00308094	
	GYNECARE TVT SECUR System - Early Surgical Experience	ETH.MESH.00370392	
	GYNECARE TVT SECUR System - Early Surgical Experience	ETH.MESH.05320911	
	Treatment of Stress Urinary Incontinence with Gynecare T	ETH.MESH.05320909	
	Risk Assessment Summary for Products In The GYNECARE TVT SECUR System	ETH.MESH.11353422	ETH.MESH.11353439
	TVT-Secur PQI07-041 - Quality Board Follow Up - Power P	ETH.MESH.06051286	
	Gynecare TVT Tension-free Support for Incontinence - Ins	ETH.MESH.02340504	ETH.MESH.02340533
	R&D BSI Project Leader Update: Thursday, July 25th - Acti	ETH.MESH.10268961	ETH.MESH.10268963

DEPOSITIONS - TESTIMONY

DEPONENT	DATE
Angelini, Laura, Transcripts and Exhibits	All dates
Arnaud, Axel, MD Transcripts and Exhibits	All dates
Barbolt, Thomas A., Ph.D Transcripts and Exhibits	10/10/2012; 08/04/2013; 08/15/2013; 01/07/2014; 01/08/2014
Batke, Boris Transcripts and Exhibits	8/1-2/2013
Beath, Catherine Transcripts and Exhibits	07/11-12/2013
Burkley, Dan Transcripts and Exhibits	5/22/2013; 5/23/2013
Cecchini, Peter Transcripts and Exhibits	10/22-23/2013
Chen, Meng, MD Transcripts and Exhibits	10/29-30/2013
Divilio, Thomas Transcripts and Exhibits	All dates
Elbert, Katrina Transcript and Exhibits	12/23/2014
Elbert, Katrina Trial Transcript and Exhibits From Perry v. Ethicon	
Grier, Douglas Transcript and Exhibits	12/30/2014
Hart, James D., MD Transcripts and Exhibits	09/17/2013; 12/20/2013
Hellhammer, Brigitte, MD Transcripts and Exhibits	09/11-12/2013
Hinoul, Piet Transcripts and Exhibits	All dates
Holste, Joerg Transcripts and Exhibits	07/29-30-2013
Horton, Ron Transcripts and Exhibits	7/1/2015
Isenberg, Richard, MD Transcripts and Exhibits	11/5/13 and 11/6/13
Jones, Greg, Transcripts and Exhibits	8/20/2013
Jones, Scot Transcript and Exhibits	6/9/2014
Kammerer, Gene, Transcript and Exhibits	All dates
Kirkemo, Aaron, Transcripts and Exhibits	All dates
Klinge de bene esse testimony and exhibits	
Lamont, Daniel J. Transcript	4/3-4/2013; 9/11/2013
Lin, Susan, Transcripts and Exhibits	3/12-13/2013; 05/3,6/2013; 08/01/2013
Lisa, Bryan Transcript and Exhibits	4/26/2013
London-Brown, Allison Transcripts and Exhibits	All dates
Longacre, Teri Transcript and Exhibits	12/19/2014
Mahmoud, Ramy Transcript and Exhibits	7/16/2013
McCoy, Sheri Transcripts and Exhibits	All dates
Owens, Charlotte Transcript and Exhibits	9/12/2012; 6/20/2013
Peebles, Rhonda Transcript and Exhibits	8/20/2014
Robinson, David Transcripts and Exhibits	07/24-25/2013; 09/11/2013
Rovner, Eric Transcript and Exhibits	All dates
Scheich, Martina Transcript and Exhibits	All dates
Selman, Renee Transcript and Exhibits	6/21/2013
Smith, Dan, Transcripts and Exhibits	05/15-16/2013; 06/04- 05/2013; 08/20-21/2013
Testimony and Exhibits from Batiste v. Ethicon Trial	
Trial Testimony of Piet Hinoul - Batiste v. Ethicon	3/26/14; 3/27/14; 3/28/14
Vailhe, Christophe, Ph.D., Transcripts and Exhibits	06/20-21/2013
Vailhe, Christophe, Ph.D., Transcripts and Exhibits	06/20-21/2013

DEPOSITIONS - TESTIMONY

Weisberg, Martin, MD Transcripts and Exhibits	All dates
Yale, Mark, Transcript and Exhibits	8/7/2013

LITERATURE

Author	Name	Journal Citation
Abbas Shobeiri S, et al	The anatomy of midurethral slings and dynamics of neurovascular injury	Int Urogynecol J (2003) 14: 185-190
Abbott S, et al.	Evaluation and management of complications from synthetic mesh after pelvic reconstructive surgery: a multicenter study	Am J Obstet Gynecol 2014; 210:163.31-8
Abbott S, Unger CA	Abbott [2014] Evaluation and management of complications from synthetic mesh after pelvic reconstructive surgery	Am J obstet Gynecol 2013;210:163.e1-8
Abdel-Fattah M, Barrington JW,et al	Pelvic pubovaginal sling versus tension-free vaginal tape for treatment of urodynamic stress incontinence: a prospective randomized three-year follow-up study	Eur Urol. 2004 Nov;46(5):629-35
Abdel-Fattah M, et al	Lower urinary tract injuries after transobturator tape insertion by different routes: a large retrospective study	GJOG 2006; 113: 1377-1381
Abdel-Fattah M, Familusi A, et al	A randomised prospective single-blinded study comparing inside-out versus outside-in transobturator tapes in the management of female stress urinary incontinence (E-TOT study): 3 years follow-up.	Neurourol Urodyn 2011;30:825-826.
Abdel-Fattah M, Ford JA, et al	Single-Incision Mini-Slings Versus Standard Midurethral Slings in Surgical Management of Female Stress Urinary Incontinence: A Meta Analysis of Effectiveness and Complications.	European Urology ,60: 468-80,24-May-11
Abdel-Fattah M, Mostafa A, et al	Prospective randomised controlled trial of transobturator tapes in management of urodynamic stress incontinence in women: 3-year outcomes from the Evaluation of Transobturator Tapes study.	Eur Urol. 2012 Nov;62(5):843-51. doi: 10.1016/j.eururo.2012.04.021. Epub 2012 Apr 14.
Abdel-fattah M, Ramsay I, et al	Evaluation of transobturator tapes (E-TOT) study: randomised prospective single-blinded study comparing inside-out vs. outside-in transobturator tapes in management of urodynamic stress incontinence: short term outcomes.	Eur J Obstet Gynecol Reprod Biol. 2010 Mar;149(1):106-11. doi: 10.1016/j.ejogrb.2009.11.023. Epub 2009 Dec 24
Abdel-Fattah M, Ramsay I,et al	Randomised prospective single-blinded study comparing 'inside-out' versus 'outside-in' transobturator tapes in the management of urodynamic stress incontinence: 1-year outcomes from the E-TOT study.	BJOG,117:870-8 ,12-Apr-10
Abdel-Fattah M, Sivanesan K, et al	How common are tape erosions? A comparison of two versions of the transobturator tension-free vaginal tape procedure.	BJU Int. 2006 Sep;98(3):594-8.

LITERATURE

Abdelnaser KH, et al	The use of polypropylene mesh as a transobturator sling for the treatment of female stress urinary incontinence (early experience with 40 cases)	Int Urogynecol J 2008; 19: 833-838
Abdelwahab O, Shedid I, et al	Tension-free vaginal tape versus secure tension-free vaginal tape in treatment of female stress urinary incontinence	Current Urology, 4 (2): 93-98
Abed H, Rahn DD, et al	"Incidence and Management of Graft Erosion, Wound Granulation, and Dyspareunia Following Vaginal Prolapse Repair with Graft Materials: A Systematic Review "	The International Urogynecology Journal,22:789-98,22-Mar-11
Abouassaly R, Steinberg JR, et al	Complications of tension-free vaginal tape surgery: a multi-institutional review.	BJU International,94:110-3 ,01-Jul-04
Abrams P et al	Synthetic Vaginal Tapes for Stress Incontinence: Proposals for Improved Regulation of New Devices in Europe	European Urology 60 (2011) 1207-1211
Abrams T	The Regulation of Prescription Drug Promotion	In Ethics and the Pharmaceutical Industry, 2005; 153-169
Achtari C, et al	Anatomical study of the obturator foramen and dorsal nerve of the clitoris and their relationship to minimally invasive slings	Int Urogynecol J (2006) 17: 330-334
ACOG	ACOG Committee Opinion 439 Informed Consent	ACOB 439 (2009)
Adile B, Granese R, Lo Bue A, et al	A prospective randomized study comparing laparoscopic Burch versus TVT: short and long term follow-up.	http://www.ics.org/Abstracts/Publish/41/000550.pdf
Afonso JS, et a	Structural and thermal properties of polypropylene mesh used in treatment of stress urinary incontinence	Acta of Bioengineering and Biomechanics (2009) 11(3):
Agarwala N.	A randomized comparison of two synthetic mid-urethral tension-free slings.	UroToday Int J. 2008 Oct;1(4)
Agatstein EH, et al	The Raz Bladder Suspensions: Treatment of Stress Urinary Incontinence: 10 Years Personal Experience	The Open Urology & Nephrology Journal, 2014, 7, 86-90
Agnew G, Dwyer PL, et al	Functional outcomes following surgical management of pain, exposure or extrusion following a suburethral tape insertion for urinary stress incontinence	Int Urogynecol J (2014) 25:235-239
AGOS	Program of the 31st Annual Meeting of the American Gynecological and Obstetrical Society	AGOS 2012
Aigmueller, T.	Reason for dissatisfaction ten years after TVT procedure	Int Urogynecol J (2014) 25;213-217
Alajmo F, et al	Polypropylene suture fracture	Ann Thorac Surg 1985; 39(4):400

LITERATURE

Alariqi SAS, et al	Biodegradation of γ -sterilised biomedical polyolefins under composting and fungal culture environments	Polym Degrad Stab 2006; 91:1105-1116
Albo ME, et al	Treatment success of retropubic and transobturator mid urethral slings at 24 months	J urology 2012 (188) 2281-2287
Albo ME, Richter HE, et al	Burch colposuspension versus fascial sling to reduce urinary stress incontinence	New England Journal of Medicine, 356:2143-55, 21-May-07
Alcalay, Menachem	Burch colposuspension: a 10-20 year follow up	British Journal of Obstetrics and Gynaecology September 1995, Vol. 102, pp. 740-745
Aldrete V	Polpropylene Suture Fracture	Ann Thorac Surg 1984 Mar; 37(3):264
Alexander	Role of Suture Materials in the Development	Ann Surg 1967; 165(2): 192-199
Ali SAM, et al	Mechanisms of polymer degradation in implantable devices 1. Polycaprolactone	Biomater 1993; 14(9): 648-658
Ali, SAM, et al	Mechanisms of polymer degradation in implantable devices 2. Poly (DL-lactic acid)	J Biomed Mater Res 1992; 27:1409-1418
Alinsod R, et al	Initial outcomes of a stabilized adjustable minisling for female urinary stress incontinence	Abstract 865 (2009)
Al-Omary R, et al	Long term patient satisfaction after suburethral sling operation for stress incontinence	Abstract 381 Int Urogynecol J (2011) ss (Suppl 3): S1769-S2008
Altman AJ, Gorn RA, et al	The breakdown of polypropylene in the human eye: is it clinically significant?	Ann Ophthalmol 1986 May; 18(5) 182-5
Altman D, Väyrynen T, et al	Anterior colporrhaphy versus transvaginal mesh for pelvic-organ prolapse.	New England Journal of Medicine, 364:1826-36, 5/12/2011
Altuna S, et al	Lower urinary tract injuries associated with the out-in transobturator tape: is cystoscopy required? An argentinean multicenter experience	Int Urogynecol J (2007) 18 (Suppl I) S163-S164
Amaro JL, Yamamoto H, et al	Clinical and quality-of-life outcomes after autologous fascial sling and tension-free vaginal tape: a prospective randomized trial	The International Brazilian Journal of Urology, 35:60-6; discussion 66-7, 01-Jan-09
Amaro, JL, et al	Clinical and quality-of-life outcomes after autologous fascial sling and tension-free vaginal tape: A prospective randomized trial	International Braz Urol (2009) 35(1): 60-67
Amat I Tardiu L, Martínez et al	Contasure-Needleless compared with transobturator-TVT for the treatment of stress urinary incontinence.	Int Urogynecol J. 2011 Jul; 22(7):827-33. doi: 10.1007/s00192-011-1380-9. Epub 2011 Mar 2.
Amid PK, et al	Biomaterials for abdominal wall hernia surgery and principles of their applications	Langenbecks Arch Chir 1994; 379:168-171
An, YH	Concise Review of Mechanisms of Bacterial Adhesion to Biomaterial Surfaces	J Biomed Mater Res (Appl Biomater) 1998; 43:338-48

LITERATURE

Anderson JM	Biodegradation of polymers	Encyclopedia of Materials Science and Technology, Pergamon, London 2001: 560-563
Anderson JM, et al	Foreign Body Reaction to Biomaterials	Semin Immunol 2008 April; 20(2): 86-100
Anderson, HA	Utilization of Adipose Tissue Biopsy in Characterizing Human Halogenated Hydrocarbon Exposure	Environ Health Perspect. 1985 May; 60:127-131
Anderson-Smits C	Developing of the Pelvic Floor Disorder Registry	www.fda.gov
Andonian S, Chen T, et al	Randomized Clinical Trial Comparing Suprapubic Arch Sling (SPARC) and Tension-Free Vaginal Tape (TVT): One-Year Results	European Urology,47:537-41,13-Jan-05
Andonian S, St-Denis B, et al	Prospective clinical trial comparing Obtape and DUPS to TVT: one-year safety and efficacy results.	Eur Urol. 2007 Jul;52(1):245-51. Epub 2007 Jan 10
Andrada Hamer M, Larsson PG, et al	"One-year results of a prospective randomized, evaluator-blinded, multicenter study comparing TVT and TVT Secur. "	Int Urogynecol J. 2013 Feb;24(2):223-9
Anger JT, Litwin MS, Wang Q, et al	Complications of sling surgery among female Medicare beneficiaries	Obstetrics & Gynecology,109:707-14,01-Mar-07
Anger JT, Weinberg AE, et al	Trends in surgical management of stress urinary incontinence among female Medicare beneficiaries	Urology,74:283-7,07-Jun-09
Angioli R, Plotti F, Muzii L, et al	"Tension-free vaginal tape versus transobturator suburethral tape: five-year follow-up results of a prospective, randomised trial"	European Urology 58 (2010) 671-677
Aniuliene R.	Tension-free vaginal tape versus tension-free vaginal tape obturator (inside-outside) in the surgical treatment of female stress urinary incontinence.	Medicina (Kaunas). 2009;45(8):639-43
Ansquer Y, Marcollet A, et al	The suburethral sling for female stress urinary incontinence: a retropubic or obturator approach?	The Journal of the American Association of Gynecologic Laparoscopists,11:353-8,01-Aug-04
Anthanasiou S, Grigoriadis T, et al	Mixed Urodynamic Incontinence: TVT or TVT-O?	Int Urogynecol J (2009) 20 (Suppl 2): S73-S239
Apple DJ, Mamalis N, et al	Biocompatibility of implant materials: a review and scanning electron microscopic study	J Am Intraocul Implant Soc 1984 Winter; 10(1):53-66
Apte, et al	Pain after suburethral sling insertion for urinary stress incontinence	Pain Practice 2012; 12(2):88-110
Araco F, Gravante G, Sorge R, et al	TVT-O vs TVT: a randomized trial in patients with different degrees of urinary stress incontinence.	The International Urogynecology Journal,19:917-26,24-Jan-08

LITERATURE

Arunkalaivanan A, et al	Efficacy and safety of transobturator tape (Obtryx™) in women with stress urinary incontinence and intrinsic sphincter deficiency: results from international Obtryx™ registry	ICS 2009 Abst. 778
Arunkalaivanan AS and Barrington JW	Randomized trial of porcine dermal sling (Pelvicol implant) vs. tension-free vaginal tape (TVT) in the surgical treatment of stress incontinence: a questionnaire-based study	Int Urogynecology J (2003) 14: 17-23
Arutchelvi J, et al	Biodegradation of polyethylene and polypropylene	Biotechnol 2008; 7:9-22
Asicioglu, O	A 5-year follow-up study comparing Burch colposuspension and transobturator tape for the surgical treatment of stress urinary incontinence.	Int J Gynecol Obstet. (2014) April 125(1): 73-77
Aslanzadeh S, et al	Photodegradation of polypropylene thermal bonded non-woven fabric	Polym Degrad Stab 2005; 90:461-470
Atassi Z, Reich A, Rudge A, et al	Haemorrhage and nerve damage as complications of TVT-O procedure: case report and literature review	Arch Gynecol Obstet 2008, 277:161-4
Athanasίου S, Grigoriadis T, et al	Seven years of objective and subjective outcomes of transobturator (TVT-O) vaginal tape: Why do tapes fail?	Int Urogynecol J. 2013 Jul 27. [Epub ahead of print]
Atherton MJ and Stanton SL.	The tension-free vaginal tape reviewed: an evidence-based review from inception to current status.	BJOG,112:534-46, 5/1/2005
Atis G, Arisan S, Ozagari A, et al	Tissue reaction of the rat urinary bladder to synthetic mesh materials.	Scientific World Journal,9:1046-51,02-Oct-09
AUA	AUA Newsletter	13-Oct
AUGS	Corporate Members"	http://www.augs.org/p/cm/ld/fid=24
AUGS/SUFU	Position Statement on Mesh Midurethral Slings for Stress Urinary Incontinence	
Avery DR	A cohort study to determine the outcome and complication rate and to classify complications using IUGA/ICS terminology following vaginal mesh for pelvic organ prolapse surgery	Int Urogynecol J (2012) 23 (Suppl 2):S43-S244
Azadi A, et al	Scanning electron microscopy (SEM) of vaginal mesh removed due to pelvic pain	Female Pelvic Med & Reconstr Surg 2013;19(5) S99 - Presentation Number: Poster 12
Azizi H, et al	Controlled-peroxide degradation of polypropylene: Rheological properties and prediction of MWD from rheological data	Polym Test 2008; 27:548-554
Bachman S, et al	An examination of spatial materials degradation of explanted polytetrafluoroethylene hernia meshes	Hernia 2009; 13(Suppl 1):S93

LITERATURE

Bachman, S, Ramshaw, B	Prosthetic Material in Ventral Hernia Repair: How Do I Choose?	Surg Clin N Am 88 (2008) 101-112
Baessler K, et al	Severe mesh complications following intravaginal slingplasty	Obstet Gynecol 2005; 106:713-6
Bai SW, Sohn WH, Chung DJ, et al	"Comparison of the efficacy of Burch colposuspension, pubovaginal sling, and tension-free vaginal tape for stress urinary incontinence"	Int J Gynaecol Obstet. 2005 Dec;91(3):246-51. Epub 2005 Oct 20
Bako A, et al	Review of synthetic mesh-related complications in pelvic floor reconstructive surgery	Int Urogynecol J DOI 10.1007/s00192-008-0717-5
Ballard, J., et al	Harnessing a Health Information Exchange to Identify Surgical Device Adverse Events for Urogynecologic Mesh	Abstract
Banks CL, et al	Abscess formation following trans-obturator tape procedures	Int Urogynecol J (2006) 17 (Suppl 2):S171-S359 Abst 204
Barber M, et al	A multicenter randomized trial comparing the transobturator tape with tension-free vaginal tape for the surgical treatment of stress urinary incontinence	Abst 113
Barber MD, Brubaker L, et al	Defining success after surgery for pelvic organ prolapse.	Obstetrics and Gynecology, 114:600-9, 01-Sep-09
Barber MD, Kleeman S, et al	Transobturator tape compared with tension-free vaginal tape for the treatment of stress urinary incontinence: a randomized controlled trial.	Obstetrics & Gynecology, 111:611-21, 01-Mar-08
Barber MD.	"Cleveland Clinic leads multicenter trial of single-incision 'minisling' for stress urinary incontinence."	Ob/GYN & Women's Health Research Perspectives. Summer 2011. clevelandclinic.org/obgyn
Barber, M., et al	Single-Incision Mini-Sling Compared With Tension-Free Vaginal Tape for the treatment of Stress Urinary Incontinence	Obstetrics & Gynecology, Vol. 119, No. 2, Part 1 (Feb 2012)
Barber, MD, et al	Validation of the Surgical Pain Scales in Women undergoing Pelvic Reconstructive Surgery	Female Pelvic Med Reconstr Surg. 2012 ; 18(4): 198-204.
Barbolt TA	Biology of polypropylene/polyglactin 910 grafts	Int Urogynecol J (2006) 17; S26-S30
Barone WR, et al	The impact of boundary conditions on surface curvature of polypropylene mesh in response to uniaxial loading	J Biomechanics, Accepted 28 Feb 2015, In Press
Barone, DVM, MS, Mark A, et al	Determinants of Postoperative Outcomes of Female Genital Fistula Repair Surgery.	Obstet Gynecol, 2012 September; 120(3); 524-531, doi:10.1097/AOG.0b013e31826579e8.

LITERATURE

Barry C, Lim YN, Muller R, et al	"A multi-centre, randomised clinical control trial comparing the retropubic (RP) approach versus the transobturator approach (TO) for tension-free, suburethral sling treatment of urodynamic stress incontinence: the TORP study"	The International Urogynecology Journal,19:171-8,19-Jul-07
Basok EK, Yildirim A, Atsu N, et al	"Cadaveric fascia lata versus intravaginal slingplasty for the pubovaginal sling: surgical outcome, overall success and patient satisfaction rates. "	Urol Int 2008;80(1):46-51
Basu M and Duckett J.	A randomised trial of a retropubic tension-free vaginal tape versus a mini-sling for stress incontinence.	BJOG 2010; 117:730-735
Beets GL, et al	Foreign body reactions to monofilament and braided - Copy	Eur J Surg 1996; 162:823-825
Bekelman JE, et al	"Scope and Impact of Financial Conflicts of Interest in Biomedical Research A Systematic Review"	JAMA, January 22/29, 2003 Vol 289 No. 4, 454-465
Bellón JM, et al	In vitro interaction of bacteria with polypropylene/ePTFE prostheses	Biomater 2001; 22:2021-2024
Bemelmans BLH, Chapple CR.	"Are slings now the gold standard treatment for the management of female urinary stress incontinence and if so which technique?"	Curr Opin Urol 2003;13:301-307
Bendavid R Iakovlev V, et al	Mesh-Related SIN Syndrome. A Surreptitious Irreversible Neuralgia and Its Morphologic Background in the Etiology of Post-Herniorrhaphy Pain	Int J Clinical Med (2014)(5) 799-810
Beranová M, et al	Degradation of polyethylene exposed in mouse-liver homogenates by oxidation	Inter Biodeterior 1990; 27:297-304
Bernstein R, et al	Radiation -- oxidation mechanisms: Volatile organic degradation products from polypropylene having selective C-13 labeling studied by GC/MS	Polym Degrad Stab 2008; 93:854-870
Berrocal J, Clave' H, et al	Conceptual advances in the surgical management of genital prolapse The TVM technique emergence	J Gynecol Obstet Biol Reprod 2004; 33:577-587
Bertin D, et al	Polypropylene degradation: Theoretical and experimental investigations	Polym Degrad and Stab 2010; 95:782-791
Bertini F, et al	Characterization and thermal degradation of polypropylene -- montmorillonite nanocomposites	Polym Degrad Stab 2006; 91: 600-605
Bezerra CA and Bruschini H.	Suburethral sling operations for urinary incontinence in women.	Cochrane Database Syst Rev.

LITERATURE

Bianchi-Ferraro AM, Jarmy-Di et al	Single-incision sling compared with transobturator sling for treating stress urinary incontinence: a randomized controlled trial.	Int Urogynecol J. 2013 Sep;24(9):1459-65. doi: 10.1007/s00192-012-1998-2. Epub 2012 Dec 4.
Bidmead J, et al	Sling techniques in the treatment of genuine stress incontinence	BJOG 2000,107(2): 147-156
Binnebosel M, et al.	Biocompatibility of prosthetic meshes in abdominal surgery	Semin Immunopathol. 2011; 33:235-243
Birolini C, Minossi JG, et al	Mesh Cancer: Long-Term Mesh Infection Leading to Squamous-Cell Carcinoma of the Abdominal Wall	Hernia,19-Apr-13
Blaivas J, Purohit R, et al	Salvage Surgery after Failed Treatment of Synthetic Mesh Sling Complications	J Urology, 2013 Oct, Vol 190, 1281-1286
Blaivas JG and Chaikin DC.	Pubovaginal fascial sling for the treatment of all types of stress urinary incontinence: surgical technique and long-term outcome.	The Urologic Clinics of North America,38:7-15,00-Jan-00
Blaivas JG, et al	Safety considerations for synthetic sling surgery	Nat. Rev. Urol. advance online publication 18 August 2015; doi:10.1038/nrurol.2015.183
Blandon, R.E., Gebhart, J.B., et al	(2009). Complications from vaginally placed mesh in pelvic reconstructive surgery.	Int. Urogynecol J Pelvic Floor Dysfunct, 20(5), 523-531. doi: 10/1007/s00192-009-0818-9.
Blitstein J, et al	A novel composite sling for the treatment of stress urinary incontinence: first clinical experience	Presented June 22, 2001, Milan, Italy, XXIII International Congress of the European Hernia Society
Blomsted B, et al	Suture material and bacterial transport. An experimental study	Acta Chir Scand 1977; 143(2):71-3 abstract
Bodelsson G, Henriksson L. et al	Short term complications of the tension free vaginal tape operation for stress urinary incontinence in women	BJOG: An International Journal of Obstetrics and Gynaecology,109:566-9,01-May-02
Bonnet P, Waltregny D, et al	Transobturator vaginal tape inside out for the surgical treatment of female stress urinary incontinence: Anatomical considerations	The Journal of Urology,173:1223-8,01-Apr-05
Bouillot JL, et al	Parietal mesh abscess as an original presentation of cancer of the caecum	Digestive Surgery (1999) 16(2) 158-160
Bowler S	Preparing articles for publication in peer-reviewed journals	American College of Preventive Medicine www.acpm.org
Boyles S, Edwards R et al.	Complications associated with transobturator sling.	Int Urogynecol J (2007) 18: 19-22
Bracco P, et al	Comparison of polypropylene and polyethylene terephthalate (Dacron) meshes for abdominal wall hernia repair: A chemical and morphological study	Hernia 2005; 9:51-55
Brill Al.	The hoopla over mesh: what it means for practice.	Obstet Gynecol News,47:14-5 ,01-Jan-12

LITERATURE

Brown BN, et al	Characterization of the host inflammatory response following implantation of prolapse mesh in rhesus macaque	Am J Obstet Gynecol 2015 Aug 7 doi 10.1016 [Epub ahead of print]
Brubaker L	Devices and meshes for the surgical treatment of prolapse and incontinence	Clinical Obstet and Gynecol 2013; 56(2):219-220
Brubaker L,	5-Year Continence Rates, Satisfaction and Adverse Events of Burch Urethropexy and Fascial Sling Surgery for Urinary Incontinence	The Journal of Urology
Brubaker L, Cundiff GW, et al	Abdominal sacrocolpopexy with Burch colposuspension to reduce urinary stress incontinence.	New England Journal of Medicine,354:1557-66,13-Apr-06
Brubaker L, Maher C, et al	Surgery for pelvic organ prolapse.	Female Pelvic Medicine & Reconstructive Surgery,16:9-19,01-Jan-10
Brubaker L, Norton PA, et al	Adverse events over two years after retropubic or transobturator midurethral sling surgery: findings from the Trial of Midurethral Slings (TOMUS) study	The American Journal of Obstetrics & Gynecology,205:498.e1-6,20-Jul-11
Brubaker L, Nygaard I, et al	Two-year outcomes after sacrocolpopexy with and without burch to prevent stress urinary incontinence.	Obstetrics and Gynecology,112:49-55, 7/1/2008
Brubaker, L.	(2006). Editorial: partner dyspareunia (hispareunia).	Int Urogynecol J Pelvic Floor Dysfunt, 17(4), 311. doi: 10.1007/s00192-006-0097-7
Brubaker, L., et al	Missing data frequency and correlates in two randomized surgical trials for urinary incontinence in women	Int Urogynecol J Published online 03/24/2015
Brubaker, L., et al.	A perfect storm.	Int Urogynecol J, 23(1), 3-4. doi: 10.1007/s00192-011-1596-8 (2012)
Bucknall	The choice of a suture to close abdominal incisions	Eur Surg Res 1983; 15(2):59-66 abstract
Buret A, et al	An in vivo model to study the pathobiology of infectious biofilms on biomaterials surfaces	J Biomed Mater Research 1991; 25: 865-874
Burns-Heffner, C., et al	Testing Compliance of Surgical Meshes Fabricated from Different Polymeric Biomaterials	Abstract #877 2014 Society for Biomaterials
Burton C, et al	Comments on Araco et al.: TVT-O vs TVT: a randomized trial in patients with different degrees of urinary stress incontinence	Int Urogynecol J 2009; 20:369
But I and Faganelj M.	Complications and short-term results of two different transobturator techniques for surgical treatment of women with urinary incontinence: a randomized study.	The International Urogynecology Journal,19:857-61,01-Jun-08
Cacciari I, et al	Isotactic polypropylene biodegradation by a microbial community: Physicochemical characterization of metabolites produced	Appl Environ Microbiol 1993; 59(11):3695-3700

LITERATURE

Cadish L, Hacker M, et al	Characterization of Pain After Inside-Out Transobturator Midurethral Sling	Female Pelvic & Reconstructive Surgery Vol 20, (2) March/April 2014
Calhoun TR, Kitten DM	Polypropylene suture -- Is it safe?	J Vasc Surg 1986; 4:98-100
Calvo JJ, Alfara AH, et al	"Stress urinary incontinence surgery with MiniArc sling system: Our experience."	Actas Urologicas Espanolas 2010;34(4):372-377
Cameron AP, et al	The treatment of female stress urinary incontinence: an evidenced-based review	Open Access J Urology 2011;3 109-120
Campagna L, et al	Transobturator (TO) T-sling (herniamesh) for the treatment of stress urinary incontinence: 3 years follow up study	IUGA Abstract 445
Campeau L, Tu LM, Lemieux MC, et al	"A Multicenter, Prospective Randomized Clinical Trial Comparing Tension-Free Vaginal Tape Surgery and No Treatment for the Management of Stress Urinary Incontinence in Elderly Women"	Neurourology and Urodynamics 26:990-994 (2007)
Cao J., et al	In Vitro Study: Synthetic Prosthetic Meshes for Inguinal Hernia Repair	Presented at AATCC International Conference May 18-20 in Atlanta, GA AATCC Review November/December 2011
Capobianco G, Dessole M, et al	TVT-Abbrevio: efficacy and two years follow-up for the treatment of stress urinary incontinence	Clin Exp Obstet Gynecol (2014); 41(4): 445-447
Caquant, F., et al.	Safety of Trans Vaginal Mesh procedure: retrospective study of 684 patients.	J Obstet Gynaecol Res. 2008; 34(4):449-456
Carey M, Higgs P, Goh J, et al	Vaginal repair with mesh versus colporrhaphy for prolapse: a randomised controlled trial.	BJOG,116:1380-6,07-Jul-09
Carey M, Slack M, et al	Vaginal surgery for pelvic organ prolapse using mesh and a vaginal support device	BJOG 2008; 115:391-397
Carr BJ, et al	Biologic response to orthopedic sutures: A histologic study in a rabbit model	Orthopedics 2009; 32(11):828
Caruso S, Rugolo S, et al	Clitoral Blood Flow Changes After Surgery for Stress Urinary Incontinence: Pilot Study on TVT Versus TOT Procedures	Urology 70: 554-557, 2007
Casiano ER, et al	Does concomitant prolapse repair at the time of midurethral sling affect recurrent rates of incontinence	Int Urogynecol J (2011) 22:819-825
Cattoni,Elena; Serati M, et al	"ISU Abs 5 Can preoperative overactive bladder (OAB) symptoms influence TVT-O outcome?"	Neurolurol and Urodyn; International Society of Urology Conference abstracts 2012
Cayan, R.	Sexual function after surgery for stress urinary incontinence: vaginal sling versus Burch colposuspension.	Gynecol Obstet. 2008 Jan; 277(1):31-6 Epub 2007 Jul 25.
Celebi I, et al	Results of the tension-free vaginal tape procedure for treatment of female stress urinary incontinence: a 5-year follow-up study.	Arch Gynecol Obstet (2009) 279: 463-467

LITERATURE

Cervigni M, Natale F, et al	Surgical Correction of Stress Urinary Incontinence Associated with Pelvic Organ Prolapse: Trans-Obturator Approach (Monarc) Versus Retropubic Approach (TVT)	Int Urogynecol J 2006;17(suppl. 2):S215 abstract 280. 31st annual IUGA meeting, Athens, Greece, 6-9 September 2006
Chae HD, Kim SR, Jeon GH, et al	A comparative study of outside-in and inside-out transobturator tape procedures for stress urinary incontinence.	Gynecol Obstet Invest. 2010;70(3):200-5. doi: 10.1159/000318866. Epub 2010 Jul 17.
Challoner, D, Korn, D	Medical Devices and the Public's Health The FDA 510(k) Clearance Process at 35 Years	Institute of Medicine of the National Academies Report Brief July 2011
Challoner, DR,	2011 - IOM Committee on the Public-Health Effectiveness of the FDA 510(k) Clearance Process - letter to FDA re 510k	IOM 2011
Challoner, DR, et al	Medical Devices and Health -- Creating a New Regulatory Framework for Moderate-Risk Devices	N Engl J Med 365:11: 977-979
Chan JH, et al	Thermal Degradation kinetics of PP Part III. Thermogravimetric analyses	Polym Degrad Stab 1977; 57:135-149
Chapple C, Raz S, Brubaker L, et al	Mesh Sling in an Era of Uncertainty: Lessons Learned and the Way Forward	European Urology 64 (2013) 525-529
Charalambous S, Touloupidis S, et al	Transvaginal vs transobturator approach for synthetic sling placement in patients with stress urinary incontinence.	Int Urogynecol J Pelvic Floor Dysfunct. 2008 Mar;19(3):357-60. Epub 2007 Aug 29.
Chen X, Tong X, Jiang M, et al	A modified inexpensive transobturator vaginal tape inside-out procedure versus tension-free vaginal tape for the treatment of SUI: a prospective comparative study	Archives of Gynecology and Obstetrics,284:1461-6 ,22-Mar-11
Chen YH, Wang YJ, Li FP, and Wang	Efficacy and postoperative complication of tension-free vaginal tape-Secur for female stress urinary incontinence	Chinese Medical Journal,124:1296-9 ,01-May-11
Chen Z, Chen Y, Du GH, et al	Comparison of three kinds of mid-urethral slings for surgical treatment of female stress urinary incontinence	Urologia. 2010 Jan-Mar;77(1):37-41; discussion 42.
Chen, et al	A modified inexpensive transobturator vaginal tape inside-out procedure versus tension-free vaginal tape for the treatment of SUI: a prospective comparative study	Arch Gynecol Obstet (2011) 284:1461-1466
Chen, X., Li, H. et al.	An inexpensive modified transobturator vaginal tape inside-out procedure for the surgical treatment of female stress urinary incontinence.	Int Urogynecol J Pelvic Floor Dysfunct 20, 1365-8 (2009).
Chene G, Cotte B et al	Clinical and ultrasonographic correlations following three surgical anti-incontinence procedures (TOT, TVT and TVT-O)	Int Urogynecol J (2008) 19:1125-1131

LITERATURE

Cheng D, Liu C.	Tension-free vaginal tape-obturator in the treatment of stress urinary incontinence: a prospective study with five-year follow-up.	Eur J Obstet Gynecol Reprod Biol. 2012 Apr;161(2):228-31. doi: 10.1016/j.ejogrb.2012.01.011. Epub 2012 Feb 13.
Chinthakanan O, et al	Mesh removal following sling/mesh placement: a multicenter study	2014-A-1236-AUGS/IUGA
Chinthakanan O, Miklos JR, et al	Indication and surgical treatment of midurethral sling complications	Int Urogynecol J (2014) 25 (Suppl 1):S144-S143
Cho MK, Kim CH, Kang WD, et al	Comparison of the clinical and quality-of-life outcomes after the inside-out TVT-O procedure with or without concomitant transvaginal gynaecological surgery.	J Obstet Gynaecol. 2012 Apr;32(3):280-4. doi: 10.3109/01443615.2011.654290
Choe JH, Kim JH, Na TG, et al	Comparative Study of Tension-Free Vaginal Tape (TVT) and Suprapubic Arc (SPARC) Sling Procedure for Female Stress Urinary Incontinence	International Urogynecology Journal 2005
Choi J, et al.	Use of Mesh During Ventral Hernia Repair in Clean-Contaminated and Contaminated Cases	Annals of Surgery, Vol 255, Number 1, Jan 2012
Cholhan HJ, et al	Pre-pubic approach to mid-urethral slings: 3-month interim report on peri-operative experience and complications	2007 Abstract
Cholhan HJ, Hutchings TB, et al	Dyspareunia associated with paraurethral banding in the transobturator sling	Am J Obstet Gynecol (2010);202:481.e1-5
Christensen LH, et al	Host tissue interaction, fate, and risks of degradable and nondegradable gel fillers	Dermatol Surg 2009; 35:1612-1619
Chrysostomou A	The management of stress urinary incontinence using transobturator tapes in a tertiary hospital in South Africa	Abst 0177 Oral presentations/Int J Gynecol & Obstet 10752 (2009) S93-S396
Chu CC	The effect of gamma irradiation on the enzymatic degradation of polyglycolic acid absorbable sutures	J Biomed Mater Res 1983; 17:1029-1040
Chung C, Kingman T, Tsai L, et al	Serious Complications From a Single-Incision Midurethral Sling Placement	Obstet & Gynecol, February 2012, Vol 119, No. 2 Part 2, 464-466
CIR Expert Panel	Final report on the safety assessment of polyethylene	Int J Toxicol 2007; 26(Suppl. 1):115-127
Claassen J	The gold standard: not a golden standard	BMJ 2005; 330: 1121
Clarke KM, Lantz GC, et al	Intestine Submucosa and Polypropylene Mesh for Abdominal Wall Repair in Dogs	Journal of Surgical Research 60, 107-114 (1996)
Clarke, EGC, et al	Discussion on metals and synthetic materials in relation to tissues	Proceedings of the Royal Society of Medicine-London 1954; 46(8): 641-652
Clavè A, et al	Polypropylene as a reinforcement in pelvic surgery is not inert: Comparative analysis of 100 explants	Int Urogynecol J 2010; 21:261-270

LITERATURE

Clave', A., et al	Polypropylene as a Reinforcement in Pelvic Surgery in Not Inert: Comparative Analysis of 100 Explants.	Int Urogyn J 2010; 21:261-270
Claymen HM	Polypropylene	Ophthalmology 1981 88:959-976
Cobb, W., et al.	The Argument for Lightweight Polypropylene Mesh in Hernia Repair	Surgical Innovation 2005, 12(1):T1-T7
Cobb, WS, et al	Textile Analysis of Heavy Weight, Mid-Weight, and Light Weight Polypropylene Mesh in a Porcine Ventral Hernia Model	J Surg Research 136, 1-7 (2006)
Coda A	Classification of prosthetics used in hernia repair based on weight and biomaterial	J Abdominal Wall Hernias (2012 Feb;16(1):9-20
Coda, A., et al	Structural Alterations of Prosthetic Mesh in Humans	Hernia. 2003; Mar;7(1):29-34
Cody, Nambiar A.	Single-incision sling operations for urinary incontinence in women (review)	Cochrane Collaboration 2014, Issue 6
Colin X, et al	Strategy for studying thermal oxidation of organic matrix composites	Compos Sci Technol 2005; 65:411-419
Collinet P, Ciofu C, et al	Safety of inside-out transobturator approach for urinary stress incontinence treatment: prospective multicentric study of 994 patients – French TVT-O registry	Int Urogynecol J (2008) 19:711-715
Colombo M, Vitabello D, et al	Randomized study to compare pereyra and TVT procedures for women with stress urinary incontinence and advanced urogenital prolapse	International Urogynecology Journal August 2005, Volume 16, Issue 2 Supplement, pp S35-S130
Comiter CV	Complications of Female Incontinence Surgery	Chapter 19
CommonHealth	Surgery Under Scrutiny: What Went Wrong With Vaginal	http://commonhealth.wbur.org/2011/1/11
Conning DM, et al	Toxicity of polypropylene in tissue culture	Fd Cosmet Toxicol 1969; 7:461-472
Constantini E, Lazzeri M, Kocjanci	"ICS Abs 3 Prolonged follow-up shows continence deterioration after transobturator tape: Results from a randomised controlled trial."	International Continence Society Mtg 2013
Contemporary OB/GYN Staff	American Urogynecologic Society voices opposition to restrictions on transvaginal mesh	Contemporary OB/GYN May 01, 2013
Cornel G	Fracture of Polypropylene Suture	Ann Thorac Surg 1982; 33:641
Cornelis R, Hogewoning C, et al	The introduction of mid-urethral slings: an evaluation of literature	Int Urogynecol J (Published online 21 August 2014))
Cornu J-N, Haab F.	Mini-slings for female stress urinary incontinence: Not yet at the age of reason.	Eur Urol 2011;60:481-483
Cornu, JN, et al	Midterm prospective evaluation of TVT-Secur reveals high failure rate	European Urology 58 (2010) 157-161
Corona, R., et al	Tension-free Vaginal Tapes and Pelvic Nerve Neuropathy	J Min Invas Gynecol 2008; 15(3):262-267

LITERATURE

Corporate Action Network	Putting Women at Risk, The Case Against Pelvic Mesh Report	Corporate Action Network August 2014
Corton M	Critical anatomic concepts for safe surgical mesh	Clin Obstet Gynecol 2013 Jun; 56(2):247-56
Coskun B, Zimmers PE, et al	Minislings can cause complications	Int Urogynecol J (2015) 26:557-562
Cosson M, et al	Mechanical properties of synthetic implants used in the repair of prolapse and urinary incontinence in women: which is the ideal materia;?	Int Urogynecol J (2003) 14: 169-178
Costa L, et al	Analysis of products diffused into UHMWPE prosthetic components in vivo	Biomater 2011; 22:307-315
Costa P	Comparisons of Safety and Efficacy of the Obtryx Sling and Advantage Mid-Urethral Sling for the Treatment of Stress Urinary Incontinence: Propensity Matching Results in a Large International Registry	Abstract 614 (2010)
Costa P, Ballanger P, et al	Transobturator Tape for SUI. Preliminary Results of Prospective Multicenter Register	ICS Abstract #379,05-Oct-03
Costa P, Grise P, et al	Surgical treatment of female stress urinary incontinence with a trans-obturator-tape (T.O.T.) Uratape: short term results of a prospective multicentric study	European Urology
Costello CR, et al	Materials Characterization of Explanted Polypropylene Hernia Meshes	J Biomed Mater Res Part B: Appl Biomater 83B: 44-49, 2007
Costello K, et al	Investigation of the mechanical strength of explanted polypropylene hernia meshes (abstract)	Poster presented at 12th annual meeting of Institute of Biological Engineering, St. Louis, MO March 29-April 1, 2007
Costello, CR, et al	Characterization of heavyweight and lightweight polypropylene mesh explants from a single patient	Surg Innov 2007;14(3):168-176
Coughlin RW, et al	Surface roughness enhances upward migration of bacteria on polymer fibers above liquid cultures	J Biomater Sci Polym Edn 1999; 10(8):827-844
Cox A, Herschorn S, et al	"Surgical management of female SUI: Is there a gold standard?"	Nat Rev Urol 2013;10:78-89
Cozad MJ, et al	Materials characterization of explanted polypropylene, polyethylene terephthalate, and expanded polytetrafluoroethylene composites: Spectral and thermal analysis	J Biomed Mater Res Part B: Appl Biomater 94B: 455-462, 2010
Crosby E, Abernethy M, et al	Symptom Resolution After Operative Management of Complications From Transvaginal Mesh	Obstet & Gynecol January 2012, Vol 123, No. 1, 134-139
Cundiff GW, Varner E, et al	Risk factors for mesh/suture erosion following sacral colpopexy.	The American Journal of Obstetrics & Gynecology,199:688.e1-5,31-Oct-08

LITERATURE

Curfman, GD., et al	Medical Devices -- Balancing Regulation and Innovation	N Engl J Med 365; 11: 975-977
Czerny J	Thermo-oxidative and photo-oxidative aging of polypropylene under simultaneous tensile stress	J App Polym Sci 1972; 16:2623-2632
Daher N, et al	Pre-pubic TVT: an alternative to classic TVT in selected patients with urinary stress incontinence	European J Obstet & Gynecol and Reproduct Biology 107 (2003) 205-207
Daly JO	Vaginal mesh products: each an entity unto itself	BJOG 2015; DOI: 10.1111/1471-0528.13534
Daneshgari F, Kong W, et al	Complications of Mid Urethral Slings: Important Outcomes for Future Clinical Trials.	The Journal of Urology Vol 180, 1890-1897 November 2008.
Daraï E, Frobert JL, et al	Functional results after the suburethral sling procedure for urinary stress incontinence: a prospective randomized multicentre study comparing the retropubic and transobturator routes.	Eur Urol 2007 Mar;51(3):795-801; discussion 801-2. Epub 2006 Sep 8
Das, N., et al	Review Article: Microbial Degradation of Petroleum Hydrocarbon Contaminants: An Overview	Biotechnology Res Int 2011: 1-13 Article ID 941810
Dati S, Cappello S, et al	Single-incision minisling (AJUST®) vs Obturator Tension-free vaginal shortened tape (TVT-Abbrevio™) in surgical management of female stress urinary incontinence	Dati poster XX FIGO World Congress of Gynecology and Obstetrics Rome, 7-12 October 2012
Dati S, et al	Obtryn (TM) system: transobturator out-in sling in the treatment of isolated or pop-associated urinary incontinence (Abstract only)	Int Urogynecol J (2007) 18 (Suppl I): S152
Dati S, Rombola P, et al	Single-Incision Minisling (Ajust) vs Obturator Tension-Free Vaginal Shortened Tape (TVT-Abbrevio) in Surgical Management of Female Stress Urinary Incontinence	Poster presentations/ Int J Gynecol & Obstet 119S3 (2012) S670
David-Montefiore E, et al	Peri-operative complications and pain after the suburethral sling procedure for urinary stress incontinence: a French prospective randomised multicentre study comparing the retropubic and transobturator routes.	European Urology,49:133-8 ,02-Nov-05
de Carvalho CL, et al	A study of the controlled degradation of polypropylene containing pro-oxidant agents	SpringerPlus 2.1 (2013): 623
de Leval J, Thomas A, and Waltregan	The original versus a modified inside-out transobturator procedure: 1-year results of a prospective randomized trial	The International Urogynecology Journal,22:145-56,21-Sep-10
de Leval J.	Novel surgical technique for the treatment of female stress urinary incontinence: Transobturator Vaginal Tape Inside-Out	European Urology,44:724-30,02-Oct-03

LITERATURE

de Oliveira LM, Girao MJBC, et al	"Comparison of Retro-Pubic TVT, Pre-Pubic TVT and TVT Transobturator in Surgical Treatment of Women With Stress Urinary Incontinence"	International Urogynecology Journal
De Ridder D, et al	Single incision mini-sling versus a transobutator sling: a comparative study on MiniArc and Monarc slings	Int Urogynecol J (2010) 21:773-778
De Souza A	Sexual function following retropubic TVT and transobturator Monarch sling in women with intrinsic sphincter deficiency: a multicentre prospective study .	Int Urogynecol J (2012) 23:153-158
de Tayrac R, Deffieux X, et al	A transvaginal ultrasound study comparing transobturator tape and tension-free vaginal tape after surgical treatment of female stress urinary incontinence.	Int Urogynecol J (2006) 17: 466-471
de Tayrac R, Droupy S, et al	A Prospective Randomized Study Comparing TVT and Transobturator Suburethral Tape (TOT) for the Surgical Treatment of Stress Incontinence	ICS Abstract #344,,05-Oct-03
de Tayrac R, et al	Basic science and clinical aspects of mesh infection in pelvic floor reconstructive surgery	Int Urogynecol J 2011; 22:775-780
de Tayrac, R et al.	Long-term anatomical and functional assessment of trans- vaginal cystocele repair using a tension-free polypropylene mesh.	Int Urogynecol J (2006) 17: 483-488.
Debodinance P, et al	Tolerance of synthetic tissues in touch with vaginal scars: review to the point of 287 cases	Euro J Obstret & Gynecol and Reprod Biology 1999; 87: 23-30
Debodinance P, Legrange E, et al	TVT Secur: Prospective Study and Follow up to 1 Year about 150 Patients	International Urogynecology Journal,19(Supp. 1):211-S12 ,00-Jan-00
Debodinance P.	Trans-obturator urethral sling for surgical correction of female stress urinary incontinence: Outside-in (Monarc) versus inside-out (TVT-O). Are the two ways reassuring?	European Journal of Obstetrics, Gynecology, and Reproductive Biology,133:232-8,21-Jun-06
Deffieux X, Daher N, et al	Transobturator TVT-O versus retropubic TVT: results of a multicenter randomized controlled trial at 24 months follow-up	Int Urogynecol J. 2010 Nov;21(11):1337-45.
Delorme E	Transobturator urethral suspension: mini-invasive procedure in the treatment of stress urinary incontinence in women	Prog Urol 2001 Dec; 11(6):1306-13
Delorme E, Droupy S, et al	Transobturator tape (Uratape): a new minimally-invasive procedure to treat female urinary incontinence	European Urology,45:203-7 ,01-Feb-04

LITERATURE

Demirkesen, O	Does vaginal anti-incontinence surgery affect sexual satisfaction? A comparison of TVT and Burch –colposuspension.	Int Braz J Urol. 2008 Mar- Apr; 34 (2):214-9
Demirkesen, O, et al	Are the effectiveness and complication rates of transoburator and tension-free vaginal tape similat?	Türk Üroloji Dergisi: 34(4): 456-462, 2008
Deng DY, et al	Presentation and Management of Major Complications of Midurethral Slings: Are Complications Under-reported?	Neurourology and Urodynamics 26:46-52 (2007)
Deng M, Chen G, et al	A Study on In Vitro Degradation Behavior of a Poly(glycolide-co-L-lactide) Monofilament	Acta Biomaterialia,4:1382-91,11-Apr-08
Deng, DY, et al	Presentation and management of major complications of midurethral slings: are complications under-reported?	Neurourol and Urodyna (2007) 26: 46-52
Deprest, et al.	The need for preclinical research on pelvic floor reconstruction	BJOG 2013; 120: 141-143
Descazeaud A, Salet-Lizée, et al	Traitement de l'incontinence urinaire d'effort par bandelette TVT-O : résultats immédiats et à un an	Gynécologie Obstétrique & Fertilité
DeSouza R, Shapiro A, et al	"Adductor brevis myosistis following transobturator tape procedure: a case report and review of the literature."	Int Urogyn J 2007;18:817-820
Detollenaere RJ, De Boon J, et al	Short term anatomical results of a randomized controlled non inferiority trial comparing sacrospinous hysteropexy and vaginal hysterectomy in treatment of uterine prolapse stage 2 or higher	Int Urogynecol J (2013) 24 (Suppl 1): S1-S152
Deval B and Haab F.	Management of the complications of the synthetic slings.	Current Opinion in Urology
Deval B, Birsan A, et al	Objective and Subjective Cure Rates After Tension-free Vaginal Tape for Treatment of Urinary Incontinence.	Urology,58: 702-706 ,01-Nov-01
Di Piazza L, Piroli Torelli D,et al	Complications in short suburethral sling positioning.	Int Urogyn J 2009;20(Suppl 3):S403-404 IUGA Abst 430
Diallo S, Cour F, et al	Evaluating single-incision slings in female stress urinary incontinence: The usefulness of the CONSORT statement criteria.	Urol 2012;80:535-541
Dietz HP, Erdman M, et al	Mesh contraction: myth or reality?	Am J Obstet Gynecol 2011 feb;204(2):173.e1-4
Dietz HP, Vancaillie P, et al	Mechanical Properties of Urogynecologic Implant Materials	The International Urogynecology Journal,14:239-43; discussion 243,05-Aug-03
Dobson A, et al	Trans-obturator surgery for stress urinary incontinence: 1-year follow-up of a cohort of 52 women	Int Urogynecol J (2006) Accepted 6 March 2006

LITERATURE

Dooley Y, et al	Urinary Incontinence Prevalence: Results From the National Health and Nutrition Examination Survey	J Urol 2008; 179: 656-661
Dougherty S, et al	Endogenous Factors Contributing to prosthetic device infections	Infect Dis Clin North Am 1989; 3(2):199-209
Drahoradova P,	Longitudinal trends with improvement in quality of life after TVT, TVT O and Burch colposuspension procedures.	Med Sci Monit. 2011; 17(2):CR67-72
Drahoradova P, Masata J, et al	Comparative Development of Quality of Life Between TVT and Burch Colposuspension	Proceedings of the 34th Annual Meeting of the International Continence Society and the International Urogynecological Association August 25-27; Paris, France (, 2004) Abstract 278
Drews RC	Polypropylene in the human eye	Am Intra-Ocular Implant Soc J 1983 Spring 9:137-142
Duckett J, Baranowski A	Pain after suburethral sling insertion for urinary stress incontinence	Int Urogynecol J (2013) 24:195-201
Duckett JR, Jain S	Groin pain after a tension-free vaginal tape or similar suburethral sling: management strategies	BJU Int. 2005 Jan;95(1):95-7
Duggan PF	Time to abolish "gold standard"	BMJ 1992; 304:1568-1569
DukeMedicine	Alert - Pelvic floor disorders Incontinence and vaginal prolapse	DukeMedicine
Dunn GE, et al	Changed Women: The Long-Term Impact of Vaginal Mesh Complications	Female Pelvic Med Reconstr Surg 2014;20: 131-136
Duong TH, Taylor D, et al	A Multicenter Study of Vesicovaginal Fistula Formation Following Cystotomy During Hysterectomy for Benign Indications	Female Pelvic Med & Reconstr Surg (2010)16(2) Supp S5-S43
Dwyer, PL	Editorial The 75% rule: all stress incontinence procedures are alike	Int Urogynecol J (2011) 22:769-770
Dyrkorn OA, Kulseng-Hanssen et al	TVT compared with TVT-O and TOT: results from the Norwegian National Incontinence Registry.	Int Urogynecol J. 2010 Nov;21(11):1321-6. doi: 10.1007/s00192-010-1195-0. Epub 2010 Jun 18.
EAU	Guidelines on Surgical Treatment of Urinary Incontinence	Published online 6 November 2012
EAU 2009:	Single-incision mid-urethral sling has high cure rate for stress urinary incontinence.	Medscape Mar 31, 2009.
Eland IA, et al	Attitudinal survey of voluntary reporting of adverse drug reactions	Br J Clin Pharmacol (1999) 48, 623-627
El-Barky E, El-Shazly A, et al	Tension free vaginal tape versus Burch colposuspension for treatment of stress urinary incontinence.	Int Urol Nephrol. 2005;37(2):277-81

LITERATURE

Elgamasy AK, et al	The use of polypropylene mesh as a transobturator sling for the treatment of female stress urinary incontinence (early experience with 40 cases).	Int Urogynecol J Pelvic Floor Dysfunct. 2008 Jun;19(6):833-8.
El-Hefnawy AS, Wadie BS, et al	TOT for treatment of stress urinary incontinence: how should we assess its equivalence with TVT?	Int Urogynecol J. 2010 Aug;21(8):947-53
Elkadry EA, et al	Patient-selected goals: A new perspective on surgical outcome	Am J Obstet Gynecol 2003;189:1551-8.)
Ellington DR and Richter HE.	"Indications, Contraindications, and Complications of Mesh in Surgical Treatment of Pelvic Organ Prolapse"	Clinical Obstetrics & Gynecology,56:276-88,01-Jun-13
Elliott CS, et al	Might pelvic surgeons be unaware of their surgical failures? Patient reporting and perceptions after failed incontinence or pelvic organ prolapse surgery	Female Pelvic Med Reconstr Surg. 2015 Sep-Oct;21(5):298-300
Elme'r C, et al	Trocar-Guided Transvaginal Mesh Repair of Pelvic Organ Prolapse	Obstet Gynecol 2009; 113:117-26)
Elser, D	New Options for Stress Urinary Incontinence	The Female Patient, Supp. Aug. 2009
ElSheemy MS, et al	Use of surgeon-tailored polypropylene mesh as a needle-less single-incision sling for treating female stress urinary incontinence: Preliminary results	Arab Journal of Urology (2015) xxx, xxx-xxx Article in press
Elzevier, Henk Willem	Female Sexual Function after Surgery for Stress Urinary Incontinence: Transobturator Suburethral Tape vs. Tension-Free Vaginal Tape Obturator	J Sex Med 2008; 5: 400-406
Endo M, et al	Mesh contraction: in vivo documentation of changes in apparent surface area utilizing meshes visible on magnetic resonance imaging in the rabbit abdominal wall model	Int Urogynecol J (2014) 25:737-743
Engelsman AF, et al	The phenomenon of infection with abdominal wall reconstruction	Biomater 2007; 28:2314-2327
Enzelsberger H, Schalupny J, et al	TVT versus TOT - A prospective randomized study for the treatment of female stress urinary incontinence at a followup of 1 year [German].	Geburtsh Frauenheilk 65:506-511
Ethicon, iNC. 2012	Sacrocolpopexy with ARTISYN™ Y-Shaped Mesh, Sales Process	ETH.MESH.08114911 - ETH.MESH.08114934
Falconer, C., et al	Influence of Different Sling Materials on Connective Tissue Metabolism in Stress Urinary Incontinent Women	Int Urogynecol J (2001) (Suppl 2):S19-S23
Farrell SA,	The evaluation of stress incontinence prior to primary surgery	J Obstet Gynaecol Can 2003;25(4):313-8

LITERATURE

Fayolle B, Audouin L, et al	Macroscopic heterogeneity in stabilized polypropylene thermal oxidation	Polymer Degradation and Stability 77 (2002) 515-522
Fayolle B, et al	Initial steps and embrittlement in the thermal oxidation of stabilized polypropylene films	Polym Degrad Stab 2002; 75:123-129
Fayolle, et al	Initial steps and embrittlement in the thermal oxidation of stabilised polypropylene films	Polymer Degradation and Stability 75 (2002) 123-129
FDA	510(k) Summary Caldera Medical Inc. T-Sling K0505165	Caladera Medical, Inc.
Feifer A and Corcos J.	The use of synthetic sub-urethral slings in the treatment of female stress urinary incontinence.	Int Urogynecol J (2007) 18:1087-1095
Feiner B and Maher C.	"Vaginal mesh contraction: definition, clinical presentation, and management. "	Obstetrics & Gynecology,115:325-30 ,01-Feb-10
Feng CL, Chin HY, Wang KH.	Transobturator vaginal tape inside out procedure for stress urinary incontinence: results of 102 patients.	Int Urogynecol J Pelvic Floor Dysfunct. 2008 Oct;19(10):1423-7. doi: 10.1007/s00192-008-0658-z. Epub 2008 May 31.
Feola A, Moalli PA, et al	Stress-Shielding the impact of Mesh Stiffness on Vaginal Function	Female Pelvic Med Reconstr. Surgery (2011) 17(5): S54-S110
Feola, A.	Deterioration in biomechanical properties of the vagina following implantation of a high-stiffness prolapse mesh	BJOG An International Journal of Obstetrics and Gynaecology 2013
Fianu, S, et al	Absorbable polyglactin mesh for retropubic sling operations in female urinary stress incontinence	Gynecol Obstet Invest 1983; 16:45-50
Firoozi F and Goldman HB.	Pure transvaginal excision of mesh erosion involving the bladder	The International Urogynecology Journal,,04-Apr-13
Firouz, Daneshgari	Complications of Mid Urethral Slings: Important Outcomes for Future Clinical Trials.2	The Journal of Urology Vol 180, 1890-1897 November 2008.
Fischer A, Fink T, et al	Comparison of retropubic and outside-in transoburator sling systems for the cure of female genuine stress urinary incontinence	European Urology,48:799-804,15-Aug-05
Flam F, Boijesen M, and Lind F.	Necrotizing fasciitis following transobturator tape treated by extensive surgery and hyperbaric oxygen.	Int Urogynecol J (2009) 20:113-115
Flemming, HC	Relevance of biofilms for the biodeterioration of surfaces of polymeric materials	Polym Degrad Stab 1998; 59:309-315
Fletcher AP	Spontaneous adverse drug reaction reporting vs event monitoring: a comparison	J Royal Society Med (1991) 84: 341-344
Flock F, Reich A, et al	Hemorrhagic complications associated with tension-free vaginal tape procedure.	Obstetrics & Gynecology,104:989-94,01-Nov-04
Flood CG, et al	Anterior colporrhaphy reinforced with Marlex mesh for the treatment of cystoceles	Int Urogynecol J Pelvic Floor Dysfunct 1998; 9(4): 200-4

LITERATURE

Food and Drug Administration (FDA).	FDA Safety Communication: Update on Serious Complications Associated with Transvaginal Placement of Surgical Mesh for Pelvic Organ Prolapse.	13-Jul-11
Foot J, et al	Referral Patterns and Complications of Midurethral Slings	Abstract 843
Ford, AA, Rogerson L, et al	Mid-urethral sling operations for stress urinary incontinence in women (Review)	The Cochran Collaboration, The Cochran Library 2015, Issue 7
Frautschi JR, et al	-Degradation of polyurethanes in vitro and in vivo comparison of different models	Colloids Surf B Biointerfaces 1993; 1:305-313
Freeman R, Holmes D, et al	What patients think: patient-reported outcomes of retropubic versus trans-obturator mid-urethral slings for urodynamic stress incontinence - a multi-centre randomised controlled trial	Int Urogynecol J. 2011 Mar;22(3):279-86
Freeman R, Holmes D, Hillard T, et al	What patients think: patient-reported outcomes of retropubic versus trans-obturator mid-urethral slings for urodynamic stress incontinence - a multi-centre randomised controlled trial	Int Urogynecol J. 2011 Mar;22(3):279-86
Frenkl TL, Rackley RR, et al	Management of Iatrogenic Foreign Bodies of the Bladder and Urethra Following Pelvic Floor Surgery	Neuro and Urodynam (2008)27:491-495
Frostling H, et al	Analytical, occupational and toxicologic aspects of the degradation products of polypropylene plastics	Scand J Work Environ Health 1984; 10:163-169
Funk MJ, Siddiqui NY, et al	Long-term Outcomes After Stress Urinary Incontinence Surgery	Obstetrics & Gynecology,120:83-90,01-Jul-12
Gallo J, et al	The relationship of polyethylene wear to particle size distribution and number: A possible factor explaining the risk of osteolysis after hip arthroplasty	J Biomed Mater Res Part B: Appl Biomater 2010; 94B:171-177
Gamble T, et al	Predicting persistent dstrusor overactivity after sling procedures	Int Urogynecol J (2008) 19 (Suppl 1): S64-S65
GAO	Medical Devices FDA Should Take Steps to Ensure That High-Risk Device Types Are Approved through the Most Stringent Premarket Review Process	GAO Report to Congressional Addressees January 2009
Garber, AM	Modernizing Device Regulation	N Engl J Med (2010) 362:13: 1161-1163
Garcia-Urena, M.A., et al	2007. Differences in polypropylene shrinkage depending on mesh position in an experimental study.	Am J Surg, 193(4), 538-542. doi: 10.1016/j.amjsurg.2006.06.045
Gebhart JB, Dixon DA, et al	Three-year outcomes of Uretex Urethral Support System for treatment of stress urinary incontinence	The International Urogynecology Journal,19:1075-9,28-Feb-08

LITERATURE

Geoffrion R, et al	Closing the Chapter on Obtape: a case report of delayed thigh abscess and a literature review	J Obstet Gynaecol Can 2008; 30(2): 143-147
Gerstenbluth, RE., et al	Simultaneous Urethral Erosion of Tension-Free Vaginal Tape and Woven Polyester Pubovaginal Sling	J Urol. 2003, Aug; 170 (2 Pt 1): 525-6
Ghoniem G, et al	Evaluation and outcome measures in the treatment of female urinary stress incontinence: International Urogynecological Association (IUGA) guidelines for research and clinical practice	Int Urogynecol J (2008) 19:5-33
Giarenis I, et al	Management of recurrent stress urinary incontinence after failed midurethral sling: a survey of members of the International Urogynecological Association (IUGA)	Int Urogynecol J 2015; 26(9):1285-1291
Giberti C, Gallo F, et al	Transobturator Tape for the Treatment of Female Stress Urinary Incontinence Objective and Subjective Results After a Mean Follow-up of Two Years	Urology,69:703-7,01-Apr-07
Gilberti C, et al	Transobturator Tape for Treatment of Female Stress Urinary Incontinence: Objective and Subjective Results After a Mean Follow-up of Two Years.	Urology 2007;69:703-707
Goldstein HS	Selecting the right mesh	Hernia 199903:23-26
Gomelsky A, et al	Biocompatibility Assessment of synthetic sling materials for female stress urinary incontinence	J Uro (2007)178:1171-1181
Goodman SB, et al	Quantitative comparison of the histological effects of particulate polymethylmethacrylate versus polyethylene in the rabbit tibia	Arth Orthop Trauma Surg 1991; 100:123-126
Goodman, SB	The histological effects of the implantation of different sizes of polyethylene particles in the rabbit tibia	J Biomed Mater Res 1990; 24:517-524
Göpferich A	Mechanisms of polymer degradation and erosion	Biomater 1995; 17:105-114
Goretzlehner U, Mullen A	PVDF as an implant material in urogynaecology	Translation of German article accepted for publishing: Journal "Biomaterialien" ISSN 1616-0177
Grant DN, et al	Conjugation of gold nanoparticles to polypropylene mesh for enhanced biocompatibility	J Mater Sci: Mater Med 2011; 22:2803-2812
Grant S, et al	Hernia meshes: new answers to an old problem	University of Missouri - Engineering 2010

LITERATURE

Greca FH	The influence of differing pore sizes on the biocompatibility of two polypropylene meshes in the repair of abdominal defects. Experimental study in dogs.	Hernia. (2001); 5: 59-64.
Greca FH, et al	The influence of differing pore sizes on the biocompatibility of two polypropylene meshes in the repair of abdominal defects	Hernia 2001; 5:59-64
Green J, Buencamino D, et al	A comparison of the transobturator tape and transabdominal tension free vaginal tape procedures for the surgical treatment of stress urinary incontinence	Presented at the 35th Annual Meeting of the International Continence Society, 28th August-2nd September 2005, Montreal, Canada.
Green TR, et al	Polyethylene particles of a critical size are necessary for the induction of cytokines by macrophages in vitro	Biomater 1998; 19:2297-2302
Greenwald D, Shumway S, et al	Mechanical Comparison of 10 Suture Materials Before and After in Vivo Incubation	J Surg Research 1994; 56:372-377
Gristina AG	Biomaterial-centered infection - microbial adhesion versus	Science 1987; 237(4822):1588-1595
Gristina, A.G.	(1987). Biomaterial-centered infection: microbial adhesion versus tissue integration.	Science, 237:1588-1595.
Groutz A, Cohen A, et al	"The safety and efficacy of the ""inside-out"" trans-obturator TVT in elderly versus younger stress-incontinent women: a prospective study of 353 consecutive patients. "	Neurourol Urolyn. 2011 Mar;30(3):380-3. doi: 10.1002/nau.20976.
Groutz A, Levin I, Gold R, et al	""Inside-out"" transobturator tension-free vaginal tape for management of occult stress urinary incontinence in women undergoing pelvic organ prolapse repair."	Urology. 2010 Dec;76(6):1358-61. doi: 10.1016/j.urology.2010.04.070. Epub 2010 Oct 25.
Groutz A, Rosen G, Gold R, et al	Long-term outcome of transobturator tension-free vaginal tape: efficacy and risk factors for surgical failure.	J Womens Health (Larchmt). 2011 Oct;20(10):1525-8. doi: 10.1089/jwh.2011.2854. Epub 2011 Aug 5.
Gryta J, et al	The influence of polypropylene degradation on the membrane wettability during membrane distillation	J Membrane Sci 2009; 326:493-502
Guelcher SA, et al	Oxidative degradation of polypropylene pelvic mesh in vitro	Int Urogynecol J (2015) 26 (Suppl 1):S55-S56
Guerrero KL, Emery SJ, et al	"A randomised controlled trial comparing TVT, Pelvicol and autologous fascial slings for the treatment of stress urinary incontinence in women "	BJOG 2010 Nov;117(12):1493-502.
Guidoin R, Chakfe N	Aneurysmal Deterioration of Arterial Substitutes	Current Therapy in Vascular Surgery 2: 324-328
Gutierrez G, et al	Thermal oxidation of clay-nanoreinforced polypropylene	Polym Degrad Stab 2010; 95:1708-1715

LITERATURE

Hafeman AE, et al	Characterization of the degradation mechanisms of lysine-derived aliphatic poly (ester urethane) scaffolds	Biomaterials 32 (2011) 419-429
Haferkamp, A., et al	Urethral Erosion of Tension-Free Vaginal Tape	J Urol. 2002;167(1): 250
Hammad FT, et al	Erosions and Urinary Retention Following Polypropylene Synthetic Sling: Australasian Surgery	Eur Urol 47 (2005) 641-647
Hammett J, et al	Short-term surgical outcomes and characteristics of patients with mesh complications from pelvic organ prolapse and stress urinary incontinence surgery	Int Urogynecol J (2014) 25:465-470
Han WHC.	Burch colposuspension or tension-free vaginal tape for female urinary incontinence? (Abstract).	International Urogynecology Journal and Pelvic Floor Dysfunction
Handa VL, et al	Banked human fascia lata for the suburethral sling procedure: a preliminary report	Obstet Gynecol 88(6): 1045-9 1996 Dec
Hansen BL, et al	Long-Term Follow-up of Treatment for Synthetic Mesh Complications	Female Pelvic Med Reconstr Surg 2014;20: 126-130
Harding CK, et al	A prospective study of surgeon and patient-perceived outcome following transobturator tape insertion for treatment of urodynamic stress incontinence	Br J Med and Surg Urol (2009) 2, 197-201
Hartung DM, et al	Reporting Discrepancies between clinicaltrials.gov results database and peer-reviewed publications	Ann Intern Med 2014;160:477-483
Hassan MF, et al	Treatment success of transobturator tape compared with tension free vaginal tape for stress urinary incontinence at 24 months: a randomized controlled trial	Open J Obstet and Gynecol, 2014, 4, 169-175
Haylen, BT, et al	An International Urogynecological Association (IUGA)/International Continence Society (ICS) joint terminology and classification of the complications related directly to the insertion of prostheses (meshes, implants, tapes) and grafts in female pelvic fl	Neurourology and Urodynamics,30:2-12,01-Jan-11
Hazell L, et al	Under-reporting of adverse drug reactions a systematic review	Drug Safety 2006; 29(5) 385-396
Hazell, L., et al	Review Article: Under-Reporting of Adverse Drug Reactions, A Systematic Review, Drug Safety 2006	Drug Safety 2006: 29(5): 385-396
Hazewinkel MH, Hinoul P, et al	Persistent groin pain following a trans-obturator sling procedure for stress urinary incontinence: a diagnostic and therapeutic challenge	The International Urogynecology Journal,20:363-5,04-Sep-08

LITERATURE

Health Canada	Health Canada Warns of Serious, Life-Altering Complications Associated with Transvaginal Mesh _ NewsInferno	http://www.newsinferno.com/health-canada-warns
Heinonen, P.	Tension-free vaginal tape procedure without preoperative urodynamic examination: Long-term outcome	International Journal of Urology (2012) 19, 1003-1009
Heise, CP, et al	Mesh Inguinodynia: A New Clinical Syndrome After Inguinal Herniorrhaphy?	J Am Coll Surg. 1998 Nov; 187(5): 514-8
Heniford, B.T.	""The benefits of lightweight meshes in Ventral Hernia Repair in Ventral Hernia Repair""	Video produced by Ethicon. 2007
Hernández-Gascón B, et al	Mechanical behaviour of synthetic surgical meshes: Finite element simulation of the herniated abdominal wall	Acta Biomaterialia 7 (2011) 3905-3913
Herniamesh	Female urinary incontinence and vaginal vault suspension: T-Sling® PP	Herniamesh publication
Hilton P	Commentary: Trials of surgery for stress incontinence -- thoughts on the 'Humpty Dumpty principle'	BJOG 2002;109:1081-1088
Hilton, P., et al	Postural Perineal Pain Associated With Perforation of the Lower Urinary Tract Due to Insertion of a Tension-Free Vaginal Tape	BJOG (2003) 110: 79-82
Hines, Jonas Zajac, et al.	Left to Their Own Devices: Breakdowns in United States Medical Device Premarket Review	PLOS Med 7(7): e1000280 July 13, 2010
Hinoul P, Bonnet P, Krofta L, et al	An anatomic comparison of the original versus a modified inside-out transobturator procedure	Int.Urogynecol J(2011) 22(8) 997-1004
Hinoul P, Roovers JP, et al	Surgical management of urinary stress incontinence in women: A historical and clinical overview.	Eur J Obstet Gyn Reprod Biol 2009;145:219-225
Hinoul P, Vanormelingen L, et al	Anatomical variability in the trajectory of the inside-out transobturator vaginal tape technique (TVT-O)	The International Urogynecology Journal,18:1201-6,24-Mar-07
Hinoul P., et al	"A Randomized, Controlled Trial Comparing an Innovative Single Incision Sling With an Established Transobturator Sling to Treat Female Stress Urinary Incontinence"	The Journal of Urology, Vol. 185, 000, April 2011 Eth.Mesh.00576529-00576540
Hiren, P, Osterguard DR, et al	Polypropylene mesh and the host response	Int Urogynecol J (2012) 23:669-679
Hogewoning CR, et al	Erratum to: The introduction of mid-urethral slings: an evaluation of literature	Int Urogynecol J 2015;26:1403-1404
Hogston P	Single surgeon experience with 125 trans-obturator sling procedures	Int Urogynecol J (2011) 22 (Suppl 3) S1947
Hohenfellner R, et al	Sling Procedures	Chapter 7 - S. L. Stanton et al., Surgery of Female Incontinence © Springer-Verlag Berlin Heidelberg 1986

LITERATURE

Hokenstad ED, et al	Health-related quality of life and outcomes after surgical treatment of complications from vaginally placed mesh	Female Pelvic Med Reconstr Surg 2015;21: 176-180
Holmgren, C	Quality of life after tension-free vaginal tape surgery for female stress incontinence	Scandinavian Journal of Urology and Nephrology, 2006; 40: 131-137
Hong MK, Liao CY, et al	Internal Pudendal Artery Injury during Prolapse Surgery Using Nonanchored Meesh	J Min Invas Gynecol (2011) 18, 678-681
Hota LS, Hanaway K, et al	TVT-Secur (Hammock) Versus TVT-Obturator: A Randomized Trial of Suburethral Sling Operative Procedures.	Female Pelvic Reconstructive Surgery,18:41-45,01-Jan-12
Hou JC, et al	Outcome of Transvaginal Mesh and Tape Removed for Pain Only	The Journal of Urology Vol 192, 856-860, September 2014
Houwert RM, Renes-Zijl C, et al	TVT-O versus Monarc after a 2-4-year follow-up: a prospective comparative study.	Int Urogynecol J Pelvic Floor Dysfunct. 2009 Nov;20(11):1327-33. doi: 10.1007/s00192-009-0943-5. Epub 2009 Jul 14.
Howden NS, Zyczynski HM, et al	Comparison of autologous rectus fascia and cadaveric fascia in pubovaginal sling continence outcomes	The American Journal of Obstetrics & Gynecology,194:1444-9,31-Mar-06
Hsiao SM, et al	Sequential comparisons of postoperative urodynamic changes between retropubic and transobturator midurethral tape procedures	World J Urol 2008 Dec;26(6):643-8
Huber A, et al	Histopathologic hosts response to polypropylene-based surgical mesh materials in a rat abdominal wall defect model	J Biomed Mater Res Part B: Appl Biomater 100B: 709-717, 2012
Hubka P, Masata J, Nanka O, et al	Possible complications of the TVT-S vaginal tape in the H-position.	ICS Abstract #286,,00-Jan-00
Hubka P, Nanka O, Martan A, et al	Anatomical study of position of the TVT-O to the obturator nerve influenced by the position of the legs during the procedure: based upon findings at formalin-embalmed and fresh-frozen bodies.	Archives of Gynecology and Obstetrics
Hurtado EA, Appell RA	Management of complications arising from transvaginal mesh kit procedures: a tertiary referral center's experience	Int Urogynecol J (2009) 20:11-17
Iakovlev V	Explanted surgical meshes: what pathologists and industry failed to do for 50 years	Virchows Arch (2014) 465 (Suppl 1) S337-
Iakovlev V, Guelcher S, et al	In vivo degradation of surgical polypropylene meshes: A finding overlooked for decades	Virchows Arch (2014) 465 (Suppl 1): S35
Iakovlev V, Mekel G, Blaivas J	Pathological Findings of Transvaginal Polypropylene Slings Explanted for Late Complications: Mesh Is Not Inert	ICS.org abst 228 Study St Michael's Hospital, Univ. Toronto
Iakovlev VV, Carey ET, Steege J	Pathology of Explanted Transvaginal Meshes	Accepted Abstract
Iakovlev, V.,	PS-24-006 Explanted surgical meshes: what pathologists and industry failed to do for 50 years	Virchows Arch (2014) 465 (Suppl 1): S337

LITERATURE

Iakovlev, V., et al	OFP-13-001 In vivo degradation of surgical polypropylene meshes: A finding overlooked for decades	Virchows Arch (2014) 465 (Suppl 1): S35
ICS	ICS Fact Sheets A Background to Urinary and Faecal Incontinence Prepared by the Publications & Communications Committee	13-Jul
Iglesia CB	Pelvic Organ Prolapse Surgery: Long-term Outcomes and Implications for Shared Decision Making	The Journal of American Medical Association,309:2045-6,15-May-13
Iglesia CB, et al	The use of mesh in gynecologic surgery	Int Urogynecol J (1997)8:105-115
Iglesia CB, Sokol AI, et al	Vaginal mesh for prolapsed: a randomized controlled trial.	Obstetrics & Gynecology,116:293-303,01-Aug-10
Iglesia, CB	Stop Using Synthetic Mesh for Routine Repair of Pelvic Organ ProlapseStart Performing Native Tissue Repairs and Reserve Mesh for Selective Cases	OBG Management 2013; 25: 24-25
Imel A, et al	In Vivo Oxidative Degradation of Polypropylene Pelvic Mesh	Biomaterials (2015), doi: 10.1016/j.biomaterials.2015.09.015.
Irwin BH, et al	Robotic-Assisted Laparoscopic Partial Nephrectomy	Chapter 4, New Technologies in Urology, John Lumley Series Editor
ISO	International Standard ISO10993-13 Identification and quantification of degradation products from polymeric medical devices	ISO10993-13
Isom-Batz G and Zimmern PE	Vaginal mesh for incontinence and/or prolapse: caution required:	Expert Rev Med Devices 2007; 4(5): 675-679
IUGA	Stress Urinary Incontinence A Guide for Women	
Jaburek L, Jaburkova J, et al	Risk of haemorrhagic complications of retropubic surgery in females: anatomic remarks	Biomedical Papers of the Medical Faculty of the University Palacky, Olomouc, Czech Republic,155:75-7,01-Mar-11
Jacquetin, B., et al	Complications of Vaginal Mesh: Our Experience	Int Urogyn J 2009; 20:893-6
Jallah Z, et al	The impact of prolapse mesh on vaginal smooth muscle structure and function	BJOG 2015; DOI: 10.1111/1471-0528.13514.
Jarman-Smith ML, et al	Porcine collagen crosslinking, degradation and its capability for fibroblast adhesion and proliferation	J Mater Sci Mater Med 2004;15:925-932
Jelovsek JE, Barber MD, et al	Randomised trial of laparoscopic Burch colposuspension versus tension-free vaginal tape: long-term follow up	BJOG,115:219-25; discussion 225,01-Jan-08
Jha, Swati	Impact of Incontinence Surgery on Sexual Function: A Systematic Review and Meta-Analysis	J Sex Med 2012; 9: 34-43
Jones, Keisha, Beola A, et al	Tensile Properties of Commonly Used Prolapse Meshes	Int Urogynecol J Pelvic Floor Dysfunct (2009); 20(7); 847-853

LITERATURE

Jongebloed, WL, et al.	Degradation of Polypropylene in the Human Eye: A Sem-Study	Doc Ophthalmol, Vol 64, No. 1, pp. 143-152, 1986
Jonsson Funk M, Siddiqui NY, et al	Long-term Outcomes After Stress Urinary Incontinence Surgery	Obstetrics & Gynecology, 120:83-90, 01-Jul-12
Juang CM, Yu KJ, Chou P, et al	Efficacy analysis of trans-obturator tension-free vaginal tape (TVT-O) plus modified Ingelman-Sundberg procedure versus TVT-O alone in the treatment of mixed urinary incontinence: a randomized study	European Urology, 51:1671-8, 16-Jan-07
Julia JJ, et al	Long term experience in 72 patients with the Advantage® sling system	www.bostonscientific.com/gynecology
Julian TM.	"The efficacy of Marlex mesh in the repair of severe, recurrent vaginal prolapse of the anterior midvaginal wall. "	The American Journal of Obstetrics and Gynecology, 175:1472-5, 01-Dec-96
Juma S and Brito CG.	Transobturator tape (TOT): Two years follow-up	Neurourol. Urodynam. (2007) 26:37-41
Jung HC, Kim JY, Lim HS, et al.	Three-year Outcomes of the IRIS procedure for Treatment of Female Stress Urinary Incontinence: Comparison with TVT Procedure.	J Korean Med Sci. (2007); 22: 497-501.
Junge K, et al	Elasticity of the anterior abdominal wall and impact for reparation of incisional hernias using mesh implants	Hernia 2001; 5:113-118
Junge, K., Rosch, R. Klinge, U. et al	Risk factors related to recurrence in inguinal hernia repair: a retrospective analysis.	Hernia (2006) 10: 309-315.
Kaelin-Gambirasio I, Jacob S, et al	Complications associated with transobturator sling procedures: analysis of 233 consecutive cases with a 27 months follow-up.	BMC Womens Health. 2009 Sep 25;9:28. doi: 10.1186/1472-6874-9-28.
Kane AR, et al	Midurethral Slings for Stress Urinary Incontinence	Clinical Obstetrics and Gynecol (2008) 51(1): 124-134
Kang D, et al	Abdominovaginal technique for complete removal of transobturator slings	Presentation
Kang D., et al	MP75-16 Patient Quality of Life After Removal of Vaginal Mesh	Urology J Vol 191, No. 4S e879
Kapoor R, et al	Is modified Raz technique of midurethral sling a reliable and cost-effective method of treating stress urinary incontinence?	Indian J Urol. 2011 JanMar 27(1): 34-38.
Karaca E, et al	Analysis of the fracture morphology of polyamide, polyester, polypropylene, and silk sutures before and after implantation in vivo	J Biomed Mater Res Part B: Appl Biomater 2008; 87B:580-589
Karateke A, Haliloglu B, Cam C, et al	Comparison of TVT and TVT-O in Patients with Stress Urinary Incontinence: Short-term Cure Rates and Factors Influencing the Outcome. A Prospective Randomised Study.	Australian and New Zealand Journal of Obstetrics and Gynaecology 2009; 49:99-105
Karram MM, Segal JL, et al	Complications and untoward effects of the tension-free vaginal tape procedure.	Obstetrics and Gynecology, 101:929-32. , 01-May-03

LITERATURE

Karsenty G, et al	Severe soft tissue infection of the thigh after vaginal erosion of transobturator tape for stress urinary incontinence	Int Urogynecol J 2007;18:207- 221
Katz S, et al	Bacterial adherence to surgical sutures a possible factor in suture induced infection	Ann Surg 1981; 194(1):35-41
Kausch HH	The Effect of Degradation and Stabilization of the Mechanical Properties of Polymers Using Polypropylene Blends as the Main Example	Macromol Symp 2005, 225: 165-178
Kavvadias T, Klinge U, Schuessler	"Ch. 56 Alloplastic Implants for the Treatment of Stress Urinary Incontinence"	Hernia Repair Sequelae , editors, V. Schumpelick, RJ Fitzgibbons, Springer-Verlag publ, 2010, pp. 439-444
Kennelly MJ, et al	Prospective evaluation of a single incision sling for stress urinary incontinence	J Urology (2010)184: 604-609
Kenton K, et al	Pelvic Floor Symptoms Improve Similarly After Pessary and Behavioral Treatment for Stress Incontinence	Female Pelvic Med Reconstr Surg. 2012 ; 18(2): 118-121.
Kenton KS, et al	Uncomplicated erosion of polytetrafluoroethylene grafts into the rectum	Obstet Gynecol 2002;187:233-4.
Kessler, DA	Introducing MEDWatch A New Approach to Reporting Medication and Device Adverse Effects and Product Problems	JAMA (1993) 269 (21): 2765-2768
Khandwala S, Lucent V, et al	Preliminary Results of Peri-Operative and 3-Month Outcomes From a World-Wide Observational Registry of Tension-Free Vaginal Tapes in Women with Stress Urinary Incontinence	ICS Abstract 493
Khanuengkitkong S, et al	Delayed vaginal and urethral mesh exposure: 10 years after TVT surgery	Int Urogynecol J (2013) 24: 519-521
Kim J, Na Y, Lee J, Seo J. et al.	Comparative Study of Tension-free Vaginal Tape (TVT) and Suprapubic arc (SPARC) Sling Procedure for Female Stress Urinary Incontinence.	V. Schumpelick, RJ Fitzgibbons, Springer-Verlag publ, 2010, pp. 439-444
Kim JY, Jung HC, Moon KH, et al	"Comparisons of IRIS, TVT and SPARC Procedure for Stress Urinary Incontinence."	European Urology Supplement
King RN, et al	Polymers in contact with the body	Environ Health Perspect 1975; 11:71-74
Kjohde, Preben	Prognostic factors and long-term results of the Burch colposuspension	Acta Obstet Gynecol Scand 1994; 73: 642-64
Klein-Patel M, et al	Ultra-lightweight synthetic mesh has similar cellular response but increased tissue ingrowth relative to heavier weight prototype	Female Pelvic Med Reconstr. Surgery (2011) 17(5): S54-S110
Klinge U, Klosterhalfen B, et al	Impact of Polymer Pore Size on the Interface Scar Formation in a Rat Model	J Surg Research 103, 208-214 (2002

LITERATURE

Klinge, U., et al	Shrinking of Polypropylene Mesh In Vivo: An Experimental Study in Dogs	Eur J Surg. 1998: 164; 965-969
Klosterhalfen	Pathology of traditional surgical nets for hernia repair after long-term implantation in humans	Chirurg 2000; 71: 43-51
Klosterhalfen B and Klinge U	Long-term Inertness of Meshes	Meshes:Benefits and Risks; Book Section D, 2004
Klosterhalfen B and Klinge U.	The lightweight and large porous mesh concept for hernia repair	Expert Rev. Med. Devices, 2005; 2(1)
Klosterhalfen B, Klinge U	Retrieval study at 623 human mesh explants made of polypropylene -- impact of mes class and indication for mesh removal on tieeus reaction	J Biomed Mater Res Part B 2013: 00B: 000-000
Kobashi KC	Management of Erosion of Graft Materials in Pelvic Floor Reconstruction	The Scientific World J (2009) 9, 32-26
Kobashi, K, et al	Management of Vaginal Erosion of Polypropylene Mesh Slings	The Journal of Urology, Vol. 169, 2242-2243 (June 2003)
Kociszewski J	Tape Functionality: Sonographic Tape Characteristics and Outcome After TVT Incontinence Surgery	Neurourol Urodynam. 27.6 (2008): 485-490
Koelbl H, Halaska M,et al	Burch Colposuspension and TVT: Perioperative Results of a Prospective Randomized Trial in Patients with Genuine Stress Incontinence.	Neurourol Urodyn 22 (2003): 327.
Kondo A, Isobe Y, Kimura K, et al	"Efficacy, Safety and Hospital Costs of Tension-free Vaginal Tape and Pubovaginal Sling in the Surgical Treatment of Stress Incontinence. "	J Obstet Gynaecol Res. 2006 Dec;32(6):539-44.
Koops, S, et al	What determines a successful tension-free vaginal tape? A prospective multicenter cohort study: Results from The Netherlands TVT database	Am J Obstet Gynecol (2006) 194. 65-74
Krause H, et al	Biomechanical properties of raw meshes used in pelvic floor reconstruction	Int Urogynecol J (2008) 19: 1677-1681
Krauth JS, Rasoamiamanana H,et al	Sub-urethral tape treatment of female urinary incontinence--morbidity assessment of the trans-obturator route and a new tape (I-STOP): a multi-centre experiment involving 604 cases	European Urology
Krofta L, et al	TVT and TVT-O for Surgical Treatment of Primary Stress Urinary Incontinence Prospective Randomized Trial.	Int Urogynecol J 2010;21:141-148
Krofta L, Feyereisl J, et al	"TVT-S for Surgical Treatment of SUI: Prospective Trial, 1-Year follow-up"	Int Urogynecol J (2010)21:779-85,
Kuehnert N, Kraemer NA	In vivo MRI visualization of mesh shrinkage usingsurgical implants loaded with superparamagnetic iron oxides	Surg Endosc. 2012 May;26(5):1468-75

LITERATURE

Kuhn, A.	Sexual function after suburethral sling removal for dyspareunia	Surg Endosc (2009) 23:765-768
Kuo HC.	Comparison of video urodynamic results after the pubovaginal sling procedure using rectus fascia and polypropylene mesh for stress urinary incontinence	The Journal of Urology,65:163-8,01-Jan-01
Kuuva N and Nilsson CG.	A nationwide analysis of complications associated with the tension-free vaginal tape (TVT) procedure	Acta Obstetrica et Gynecologica Scandinavica ,81:72-7,01-Jan-02
Kuuva, N, et al.	Long-term results of the tension-free vaginal tape operation in an unselected group of 129 stress incontinent women	Acta Obstetrica Gynecologica Scandanavica 2006(85: 4 482-87)
Kwon SY, Latchamsetty KC, et al	Inflammatory Myofibroblastic Tumor of the Urinary Tract Following a TVT	Female Pelvic Medicine & Reconstructive Surgery,18:249-51,01-Jul-12
Labrie J, van der Graaf Y,et al	Protocol for physiotherapy OR TVT Randomised efficacy trial (PORTRET): a multicenter randomized controlled trial to assess the cost-effectiveness of the tension free vaginal tape versus pelvic floor muscle training in women with symptomatic moderate to s	BMC Women's Health 2009;9:24-32
Lapitan MC, Cody JD, and et al	Open retropubic colposuspension for urinary incontinence in women.	Cochrane Database of Systematic Reviews ,CD002912,21-Jan-09
Latthe PM, Foon R, and Tooze-Hobso	Transobturator and retropubic tape procedures in stress urinary incontinence: a systematic review and meta-analysis of effectiveness and complications	BJOG 2007; 114:522-531
Latthe PM, Singh P, Foon R, et al	Two routes of transobturator tape procedures in stress urinary incontinence: a meta-analysis with direct and indirect comparison of randomized trials.	BJUI 2009; 106:68-76
Laurikainen E, Takala T,et al	Retropubic TVT Compared with Transobturator TVT (TVT-O) in Treatment of Stress Urinary Incontinence: Five-year Results of a Randomized Trial.	Obstetrics & Gynecology 109.1 (2007): 4-11.
Laurikainen E, Valpas A, et al	Retropubic compared with transobturator tape placement in treatment of urinary incontinence: a randomized controlled trial	Obstetrics & Gynecology
Lee D, Bacsu C, et al	Meshology: a fast-growing field involving mesh and/or tape removal procedures and their outcomes	Expert Rev. Med Devices Early online 1-16 (2014
Lee D, Dillon B, Lemack G, et al	"Transvaginal Mesh Kits-- How "Serious" Are the Complications and Are They Reversible?"	Urology 81: 43-49, 2013

LITERATURE

Lee KS, Choo MS, Lee YS, et al	Prospective comparison of the 'inside-out' and 'outside-in' transobturator-tape procedures for the treatment of female stress urinary incontinence	Int Urogynecol J. (2008) 19:577-582.
Lee KS, Han DH, Choi YS, et al	A prospective trial comparing tension-free vaginal tape and transobturator vaginal tape inside-out for the surgical treatment of female stress urinary incontinence: 1-year follow up.	J Urology (2007) 177: 214-218
Lemer ML, et al	The use of artificial material in sling surgery	Chapter 41 - The Urinary Sphincter 2001
Lensen EJM, et al	Comparison of two trocar-guided trans-vaginal mesh systems for repair of pelvic organ prolapse: a retrospective cohort study	Int Urogynecol J 2013; 24: 1723-1731
Levin I, Groutz A, Gold R, et al	Surgical Complications and Medium-term Outcome Results of Tension-free Vaginal Tape: A Prospective Study of 313 Consecutive Patients.	Neurology and Urodynamics ,23:7-9,01-Jan-04
Levy, B., et al	Best Options, Techniques, and Coding Tips for Pelvic Prolapse Repair	OBG Management Supp.Sept. 2007; S1-S12
Li B, Zhu L, Lang J, Fan R, et al	Long-term Outcomes of the Tension-Free Vaginal Tape Procedure for Female Stress Urinary Incontinence: 7-Year Follow-up in China	J Min Invas Gynecol 2012; 19(2):201-205
Li X, et al.	Characterizing the ex vivo mechanical properties of synthetic polypropylene surgical mesh	J Mechanical Behavior Biomedical Materials (2014) 48-55
Liang R, Abramowitch S, et al	Vaginal Degeneration Following Implantation of Synthetic Mesh With Increased Stiffness	BJOG (2013); 120(2): 233-243
Liang R, et al	Increasing stiffness of synthetic mesh negatively impacts vaginal connective tissue	Female Pelvic Med Reconstr. Surgery (2011) 17(5): S54-S110
Liapis A, Bakas P, and Creatsas G.	Monarc vs. TVT-O for the treatment of stress incontinence: a randomized study	Int Urogynecol J (2008) 19:185-190
Liapis A, Bakas P, Creatsas G.	Burch Colposuspension and Tension-free Vaginal Tape in the Management of Stress Urinary Incontinence in Women.	Eur Urol. 41 (2002):469-473.
Liapis A, Bakas P, et al	Tension-free Vaginal Tape for Elderly Women with Stress Urinary Incontinence.	International Journal of Gynecology & Obstetrics (2006) 92, 48-51
Liapis A, Bakas P, Giner M, et al	Tension-free vaginal tape versus tension-free vaginal tape obturator in women with stress urinary incontinence	Gynecol Obstetric Invest 62:160-164
Liebert TC, et al	Subcutaneous Implants of Polypropylene Filaments	J Biomed Mater Res 1976; 10:939-951
Liedl B, et al	A review and critical analysis of historical operations for cure of urinary stress incontinence. Part 2- abdominal sling operations	Pelvipereineology 2014; 33: 68-73

LITERATURE

Lim JL, Cornish A, et al	Clinical and quality-of-life outcomes in women treated by the TVT-O procedure.	BJOG. 2006 Nov;113(11):1315-20.
Lim JL, Quinlan DJ.	Safety of a new transobturator suburethral synthetic sling (TVT-O) procedure during the training phase.	J Obstet Gynaecol Can. 2006 Mar;28(3):214-7.
Lim YN, et al	Do the Advantage slings work as well as the tension-free vaginal tapes?	Int Urogynecol J (2010) 21:1157-1162
Lim YN, Muller R, et al	"Suburethral slingplasty evaluation study in North Queensland, Australia: the SUSPEND trial."	Australian and New Zealand Journal of Obstetrics and Gynaecology,45:52-9,24-Feb-05
Lin ATL, Wang SJ, et al	In vivo tension sustained by fascial sling in pubovaginal sling surgery for remale stress urinary incontinence	J Urology (2005) 173: 894-897
Lithner, Delilah	Environmental and health hazards of chemicals in plastic polymers and products	Doctoral Thesis, Department of Plant and Environmental Sciences, 2011
Litwiller JP, et al	Effect of lithotomy positions on strain of the obturator and lateral femoral cutaneous nerves	Clin Anat 2004 Jan; 17(1): 45-9
Litwiller, SE et al	Presentation Number: Poster 109 Long term efficacy and safety of the Obtryx tm (Boston Scientific Corp.) sling for treatment of stress urinary incontinence in a community setting: an analysis of outcomes and quality of life	J Pelvic Med & Surg (2009) 12(5) 353
Liu PE, Su CH, Lau HH, et al	Outcome of tension-free obturator tape procedures in obese and overweight women.	Int Urogynecol J. 2011 Mar;22(3):259-63. doi: 10.1007/s00192-010-1311-1. Epub 2010 Nov 12.
Lord HE, Taylor JD, et al	A randomized controlled equivalence trial of short-term complications and efficacy of tension-free vaginal tape and suprapubic urethral support sling for treating stress incontinence.	BJU International,96:367-76,01-Aug-06
Lowenstein L, et al	Patients' pelvic goals change after initial urogynecologic consultation	Am J Obstet Gynecol 2007; 197:640.e1-640.e3.
Lowry, F	EAU 2009 Single-incision mid-urethral sling has high cure rate for stress urinary incontinence	Medscape. Mar 31, 2009
Lucas M, Emery S, Alan W, et al	Failure of porcine xenograft sling in a randomised controlled trial of three sling materials in surgery for stress incontinence (Abstract).	Proceedings of the International Continence Society (34th Annual Meeting) and the International UroGynecological Association. 2004.
Lucas MG, et al	EAU Guidelines on Surgical Treatment of Urinary Incontinence (Short Version)	Euro Urol 2012; 62:1118-1129
Luongo JP	Infrared Study of Polypropylene	J Appl Polym Sci 1960; 3(9):302-309

LITERATURE

Mahajan ST, et al	Transobturator tape erosion associated with leg pain	Int Urogynecol J (2005) 17: 66-68
Maier C, Qatawneh A, et al	Laparoscopic Colposuspension or Tension-free Vaginal Tape for Recurrent Stress Urinary Incontinence and/or Intrinsic Sphincter Deficiency in a Randomized Controlled Trial.	Neurourol Urodyn 2004; 23:433-434
Mahmoud, W.M., Vieth, R.F., et al.	Migration of bacteria along synthetic polymeric fibers.	J Biomater Sci Polym Ed, 4(6):567-578
Mamy L, et al	Correlation between shrinkage and infection of implanted synthetic meshes using an animal model of mesh infection	Int Urogynecol J 2011; 22:47-52
Mansoor A, Védrine N et al	Surgery of female urinary incontinence using transobturator tape (TOT): a prospective randomised comparative study with TVT (Abstract).	Neurourology and Urodynamics 22.5 (2003): 88-88.
Marcus-Braun N, Bourret A, et al	Persistent pelvic pain following transvaginal mesh surgery: a cause for mesh removal	Euro J Obstet & Gynecol and Reprod Bio 162 (2012) 224-228
Marcus-Braun N, von Theobald P	Mesh removal following transvaginal mesh placement: a case series of 104 operations.	Int Urogynecol J (2010) 21:423-430
Marks B, Goldman H	Controversies in the Management of Mesh-Based Complications: A Urology Perspective	Urol Clin N Am 39 (2012) 419-428
Marsh F and Rogerson L.	Groin abscess secondary to trans obturator tape erosion: case report and literature review.	Neurol Urodynam 26:543-546, 2007
Martin JR, et al	A porous tissue engineering scaffold selectively degraded by cell-generated reactive oxygen species	Biomaterials 35 (2014) 3766-3776
Martinez-Fornes	A three year follow-up of a prospective open randomized trial to compare tension-free vaginal tape with Burch colposuspension for treatment of female stress urinary incontinence	Actas Urol Esp. 2009 Nov;33(10):1088-96
Mary, Celine, et al	Comparison of the In Vivo Behavior of the Polyvinylidene Fluoride and Polypropylene Sutures Used In Vascular Surgery	ASAIO Journal 1998: 199-206
Masata J, Svabik K, et al	Randomized Prospective Trial of a Comparison of the Efficacy of TVT-O and TVT SECUR System in the Treatment of Stress Urinary Incontinent Women – Comparison of the Long- and Short-Term Results	Neurourol Urodyn 2011;30:805-806
Masata J, Svabik K, Hubka P, et al	ICS Abs 6 Is the fixation of single incision tape (TVT-S) as good as a transobturator tape (TVT-O)? An ultrasound study, results from randomized trial.	International Continence Society Mtg 2012

LITERATURE

Masata J, Svabik K, Zvara K, et al	Randomized trial of a comparison of the efficacy of TVT-O and single-incision tape TVT SECUR systems in the treatment of stress urinary incontinent women--2-year follow-up.	Int Urogynecol J. 2012 Oct;23(10):1403-12.
May, J, et al	M429 OUTCOME OF OBTRYX	Poster presentations / Inte J Gynecol & Obstet 11953 (2012) S531-S867
Mazouni, Chafika	Urinary complications and sexual function after the tension-free vaginal tape procedure	Acta Obstetricia et Gynecologica Scandinavica volume 83 Issue 10 pages 955-961 October 2004
McCracken, G.R.	Five Year Follow-Up Comparing Tension-Free Vaginal Tape and Colposuspension	Ulster Med J 2007; 76(3) 146-149
McFadden BL, et al	Patient recall 6 weeks after surgical consent for midurethral sling using mesh	Int Urogynecol J (2013) 24:2099-2104
McNanley AR, et al	Poster Presentation Abstracts 108 Recovery after robotic sacrocolpopexy: the patient's perspective	J Pelvic Med & Surg (2009) 12(5) 353
Medscape	Surgical Management of UI and Pelvic Prolapse: 2006 AUA Results	Medscape
Meier, B	Group Faults the FDA on Oversight of Devices	New York Times 04/12/2011
Mellier G, Benayed B, et al	Suburethral tape via the obturator route: is the TOT a simplification of the TVT?	Int Urogynecol J (2004) 15: 227-232
Merritt K, et al	Factors Influencing Bacterial Adherence to Biomaterials	J Biomater Appl 1991; 5: 185-203
Meschia M, Bertozzi R, et al	Peri-operative morbidity and early results of a randomised trial comparing TVT and TVT-O	Int Urogynecol J (2007) 18: 1257-1261
Meschia M, Pifarotti P, et al	Tension-free Vaginal Tape (TVT) and Intravaginal Slingplasty (IVS) for Stress Urinary Incontinence: a Multicenter Randomized Trial.	Am J Obstet Gynecol. 2006 Nov;195(5):1338-42. Epub 2006 Jun 12
Mesens T, et al	Late erosions fo mid-urethral tapes for stress urinary incontinence--need for long-term follow-up?	Int Urogynecol J 2007; 18:1113-1114
Meyer CP, et al	Complications After Surgery for Stress Urinary Incontinence Untangling a Mesh of Uncertainties	JAMA Surgery Published online September 9, 2015: E1
Miklos JR, Chinthakana O, et al	The IUGA_ICS classification of synthetic mesh complications in femals pelvic floor reconstructive surgery: A multicenter study	Int Urogynecol J (2014) 25 (Suppl 1):S140-S141
Milani R, Salvatore S, et al	Functional and anatomical outcome of anterior and posterior vaginal prolapse repair with prolene mesh.	BJOG (2005)112:107-111
Miller D, Lucente V, et al	Prospective clinical assessment of the transvaginal mesh technique for treatment of pelvic organ prolapse-5-year results.	Female Pelvic Med Reconstr Surg 2011; 17: 139-143

LITERATURE

Miller JR, Botros SM, et al	Comparing stress urinary outcomes of tension free vaginal tape with transobturator tape sling: a retrospective cohort study	Presented at ICS 2005, 35th annual meeting of the International Continence Society, Aug. 31-Sept. 2, 2005, Montreal, Canada.
Mirosh M and Epp A.	TVT vs laparoscopic Burch colposuspension for the treatment of stress urinary incontinence.	http://www.ics.org/Abstracts/Publish/43/00640.pdf
Mischinger J, et al	Different surgical approaches for stress urinary incontinence in women	Minerva Ginecol 2013; 65: 21-8
Misrai V, Roupret M, et al	Surgical resection for suburethral sling complications after treatment for stress urinary incontinence	J Urol 2009 May;181(5):2198-202; discussion 2203
Moalli J Editor	Plastics Failures, Analysis and Prevention	2001, Chapters 1 and 6
Moalli, P., et al	Tensile Properties of Five Commonly Used Mid-Urethral Slings Relative to the TVT	Int Urogynecol J (2008) 19:655-663
Moghaddam L, et al	Investigation of polypropylene degradation during melt processing using a profluorescent nitroxide probe: A laboratory-scale study	Polym Degrad Stab 2011; 96: 455-461
Montoya TI, et al	Anatomic relationships of pudendal nerve branches	Am J Obstet Gynecol 2011; 205: 504.e1-5
Moon, HB., et al	Occurrence and Accumulation Patterns of Polycyclic Aromatic Hydrocarbons and Synthetic Musk Compounds in Adipose Tissues of Korean Females.	Chemosphere. (2012) 86:485-90
Moore R, Mitchell G, et al	"ICS Abs 827 MiniArc single incision sling: 1 year follow-up on a new minimally invasive treatment for female SUI."	International Continence Society Mtg 2009
Moore RD, et al	Minimally Invasive Treatment for Female Stress Urinary Incontinence	Expert Rev Obstet Gynecol 3(2), 257-272 (2008)
Moore RD, Miklos JR.	Single incision mini-sling. 1 year follow-up on a new minimally invasive treatment for female SUI.	Int Urogyn J 2009;20(Suppl 3):S312-313 IUGA Abs 298
Moore WS, Hall AD	Late Suture Failure in the Pathogenesis of Anastomotic False Aneurysms	Annals of Surgery 172.6 (1970):1064-1068
Morey AF, Medendorp AR, et al	Transobturator versus transabdominal mid urethral slings: a multi-institutional comparison of obstructive voiding complications	J Urology, (2006)175:1014-1017
Moride Y, et al	Under-reporting of adverse drug reactions in general practice	Br J Clin Pharmacol 1997; 43: 177-181
Morley R and Nethercliffe J.	Minimally invasive surgical techniques for stress incontinence surgery.	Best Practice & Research Clinical Obstetrics & Gynaecology ,19:925-40,07-Nov-05
Morton HC, et al	Urethral injury associated with minimally invasive mid-urethral sling procedures for the treatment of stress urinary incontinence: a case series and systematic literature search	BJOG 2009;116:1120-1126

LITERATURE

Mostafa A, Agur W, et al	A multicentre prospective randomised study of single-incision mini-sling (Ajust®) versus tension-free vaginal tape-obturator (TVT-O) in the management of female stress urinary incontinence: pain profile and short-term outcomes.	Eur J Obstet Gynecol Reprod Biol. (2012);165:115-21.
Mostafa A, et al	Single-incision mini-slings versus standard midurethral slings in surgical management of female stress urinary incontinence: An updated systematic review and meta-analysis of effectiveness and complications	Eur Urol 2014;65:4-2-427.
Mourtzinou A, et al	Editorial comment: Advances in female stress urinary incontinence: mid-urethral slings	BJU International 2001; 98 Supp 1; 41-42
Mouzon, N, Garome, M, et al.	Substantially Unsafe Medical Devices Pose Great Threat to Patients; Safeguards Must be Strengthened, Not Weakened	Public Citizen, February 2012
Mueller, ER	Retropubic Bladder Neck Suspensions	In H.B. Goldman (Ed.), Complications of Female Incontinence and Pelvic Reconstructive Surgery (pp. 107-114): Humana Press
Mueller, ER, et al	Are we missing an opportunity to teach future physicians about female pelvic floor disorders?	Int Urogynecol J (2009) 20:1413-1415
Muffy TM, et al	Interventional Radiologic Treatment of pelvic hemorrhage after placement of mesh for reconstructive pelvic surgery	Obstet Gynecol 2012; 119:459-62
Muir TW, Tulikangas PK, et al	The Relationship of Tension-Free Vaginal Tape Insertion and the Vascular Anatomy	Obstetrics & Gynecology,101:933-6,01-May-03
Murphy M, van Raalte H, et al	"Incontinence-related quality of life and sexual function following the tension-free vaginal tape versus the ""inside-out"" tension-free vaginal tape obturator."	Int Urogynecol J (2008) 19:481-487
Murray S, et al	Urethral distortion after placement of synthetic mid urethral sling	J Urol 2011; 185:1321-1326
Murray, S., et al	Mesh kits for anterior vaginal prolapse are not cost effective	Int Urogynecol J, 2011; 22(4), 447-452. doi: 10.1007/s00192-010-1291-1 (2011)
Mustafa M, et al	Bladder erosion of tension-free vaginal tape presented as vesical stone; management and review of literature	Int Urol Nephrol 2007; 39:453-455
N/A	Emedicine – Medscape.com (2013) Burch colposuspension	
Narang S, Han HC	Initial Experience of TVT-Abbrevio at a Tertiary Care Hospital	ICS Abs. 682

LITERATURE

Narang, S, et al	TVT Abbrevio for management of remale stress urinary incontinence - A prospective analysis over 22 months in a tertiary care hospital	Narang abstract poster
Naumann G, Lobodasch K,et al	Tension free vaginal tape (TVT) vs less invasive free tape (LIFT)-a randomized multicentric study of suburethral sling surgery.	http://www.ics.org/Abstracts/Publish/44/000481.pdf
Navarro, RF, et al	Elastic properties of degraded polypropylene	J Mater Sci 2007; 42:2167-2174
Nazemi TM, Yamada B, et al	Minimum 24-Month Followup of the Sling for the Treatment of Stress Urinary Incontinence	The Journal of Urology,179:596-9,21-Dec-07
Neuman M, Sosnovski V, et al	Transobturator vs single-incision suburethral mini-slings for treatment of female stress urinary incontinence: early postoperative pain and 3-year follow-up.	J Minim Invasive Gynecol. (2011) 18: 769-773
Neuman M.	TVT and TVT-Obturator: comparison of two operative procedures.	European Journal of Obstetrics & Gynecology and Reproductive Biology (2007) 131: 89-92
Neuman, M, Sosnovski V, et al	Comparison of two inside-out transobturator suburethral sling techniques for stress incontinence: Early postoperative thigh pain and 3-year outcomes	Int J Urol (2012) 19: 1103-1107
Nezhat FR, et al	Robotic-assisted laparoscopic transection and repair of an obturator nerve during pelvic lymphadenectomy for endometrial cancer	Obstet Gynecol 2012; 119: 462-4
Nguyen JN and Burchette RJ.	Outcome after anterior vaginal prolapsed repair: a randomized controlled trial.	Obstetrics & Gynecology (2008),111 (4):891-898
Nguyen JN, Jakus-Waldman SM, et al	Perioperative complications and reoperations after incontinence and prolapse surgeries using prosthetic implants.	Obstetrics & Gynecology, (2012)119(3):539-546
NICE	Eighth Report of Session 2012-13 Volume II	
NICE Guidance	http://guidance.nice.org.uk/index.jsp?action=article&o=32572	
Nieminen K, Hiltunen R, et al	"Outcomes after anterior vaginal wall repair with mesh: a randomized, controlled trial with a 3 year follow-up"	Am J Obstet Gynecol,(2010)203:235.e1-8
Nilsson C.G., et al	Reprint: Long-term Results of the Tension-Free Vaginal Tape (TVT) Procedure for Surgical Treatment of Female Stress Urinary Incontinence	Int Urogynecol J (2001)(Supp. 2):S5-S8 Eth.Mesh.00159481-00159484
Nilsson CG, et al	Seventeen years' follow-up of the tension-free vaginal tape procedure for female stress urinary incontinence	Int Urogynecol J March 2013 Published online 04/06/2013
Nilsson CG., et al	Seven-Year Follow-up of the Tension-Free Vaginal Tape Procedure for Treatment of Urinary Incontinence	Obstetrics & Gynecology, Vol. 104, No. 6 (Dec 2004)

LITERATURE

Nilsson, C	Creating a gold standard surgical procedure: the development and implementation of TVT	Int Urogynecol J DOI 10.1007/s00192-014-2616-2 (2015)
Nilsson, Carl G.	Creating a gold standard surgical procedure: the development and implementation of TVT	Int. Urogynecol J (2015) 26: 467-469
Nilsson, CG, et al	Eleven years prospective follow-up of the tension-free vaginal tape procedure for treatment of stress urinary incontinence ²	Int Urogynecol J (2008) 19:1043-1047
Nilsson, CG., et al	Long-term Results of the Tension-Free Vaginal Tape (TVT) Procedure for Surgical Treatment of Female Stress Urinary Incontinence	Int Urogynecol J (2001) (Suppl 2): S5-S8
Noblett KL, Shen B, et al	Lynx midurethral sling system: a 1-year prospective study on efficacy and safety	5479411
Norton, P	New technology in gynecologic surgery. Is new necessarily better?	Obstet & Gynecol (2006)108(3)2:707-708
Nossier S, et al	Presentation Number: Poster 30 Safety and efficacy of the Solyx™ single-incision sling system	Female Pelvic Medicine & Reconstructive Surgery (2010) 16(5)2:S110-S1111
Novara G, Ficarra V, et al	Tension-free midurethral slings in the treatment of female stress urinary incontinence: a systematic review and meta-analysis of randomized controlled trials of effectiveness.	Eur Urol. (2007)52:663-678.
Novara G, Galfano A, et al	Critical Assessment of Pelvic Floor Surgical Reconstruction Outcome	EAU-EBU Update Series 4 (2006) 202-213
Nygaard I, Barber MD, et al	Prevalence of symptomatic pelvic floor disorders in US women.	JAMA (2008); 300(11):1311-1316
Nygaard I, Brubaker L, et al	Long-term Outcomes Following Abdominal Sacrocolpopexy for Pelvic Organ Prolapse	JAMA (2013);309(19):2016-2024,
Nygaard IE, McCreery R, et al	Abdominal sacrocolpopexy: a comprehensive review.	Obstet & Gynecol (2004)104(4):805-823
Nygaard, I	Approval Process for Devices and Mesh for Surgical Treatment of Pelvic Organ Prolapse and Urinary Incontinence	Clinical Obstet and Gynecol (2013) 56(2): 229-231
Obadal M, et al	Structure evolution of α - and β -polypropylenes upon UV irradiation: A multi-scale comparison	Polym Degrad Stab 2005; 88(3):532-539.
Ogah J, Cody DJ, and Rogerson L.	Minimally invasive synthetic suburethral sling operations for stress urinary incontinence in women: a short version Cochrane Review	Neurourology and Urodynamics(2011)30:284-291
OHSU	Clinical trial results inconsistently reported among journals, government website _ News _ OHSU	03/31/14 Portland, Ore.
Okulu E, et al	Use of three types of synthetic mesh material in sling surgery: A prospective randomized clinical trial evaluating effectiveness and complications	Scandinavian Journal of Urology, 2013; 47: 217-224

LITERATURE

Okulu E, Kayigil O, et al	Use of three types of synthetic mesh material in sling surgery - a prospective randomized clinical trial evaluating effectiveness and complications	Scandinavian J Urology 2013; 47: 217-224
Oliveira R, Botelho F, et al	Exploratory Study Assessing Efficacy and Complications of TVT-O, TVT-Secur, and Mini-Arc: Results at 12-Month Follow-up.	European Urology (2011) 59: 940-44
Ortega-Castillo V and Neri-Ruz ES.	Chapter 15: Surgical Complications with Synthetic Materials	Urinary Incontinence (book published by InTech),241-62,02-Apr-12
Osborn, D.J. et al.	Analysis of patient and technical factors associated with midurethral sling mesh exposure and perforation	Int J Urol (2014) 21, 1167-1170
Osmundsen B, et al	Tension-free vaginal tape failure after robotic sacrocolpopexy and tension-free vaginal tape for concomitant prolapse and stress incontinence	Female Pelvic Med Reconstr Surg 2015;21:244-248
Osterberg B	Enclosure of bacteria within capillary multifilament sutures as protection against leukocytes	Acta Chir Scand 1983; 149(7):663-668 abstract
Osterberg, B., et al	Effect of Suture Materials on Bacterial Survival in Infected Wounds. An Experimental Study	Acta Chir Scand. 1979; 145(7):431-4
Ostergard, Donald R.	Degradation, infection and heat effects on polypropylene mesh for pelvic implantation: what was known and when it was known.	Int Urogynecol J, 22:771-774.
Ostergard, DR	Polypropylene Baginal Mesh Grafts in Gynecology	Obstet Gynecol 1020; 116:962-966
Oswald JF, Turi E	The Deterioration of Polypropylene By Oxidative Degradation	Polymer Engineering and Science 5 (1965) 152-158
Ozel B, et al	The impact of pelvic organ prolapse on sexual function in women with urinary incontinence	Int Urogynecol J (2005) 17: 14-17
Ozog Y., et al	Shrinkage and biomechanical evaluation of lightweight synthetics in a rabbit model for primary fascial repair	Int Urogynecol J published online: 12 May 2011
Palma P, et al	Arcus to acrus microsling: technique and preliminary results	Int Urogynecol J Accepted 23 February 2008
Palva K, Rinne K, et al	A randomized trial comparing tension-free vaginal tape with tension-free vaginal tape-obturator: 36-month results	Int Urogynecol J(2010) 21: 1049-1055
Pandit AS, Henry, JA	Design of surgical meshes -- an engineering perspective	Technology and Health Care 12 (2004) 51-65
Paraiso MF, Walters MD, et al	Laparoscopic Burch Colposuspension versus Tension-free vaginal tape: a randomized trial	Obstetrics & Gynecology (2004)104(6):1249-1258

LITERATURE

Parden AM, Gleason JL, et al	Incontinence outcomes in women undergoing primary and repeat midurethral sling procedures.	Obstet Gynecol (2013);121(201):273-278
Pariente, JL	An independent biomechanical evaluation of commercially available suburethral slings	Issues in Women's Health Eth.MESH.01221055
Pariente, JL.	Mechanical evaluation of various suburethral tapes used for the treatment of stress urinary incontinence.	(2005) Progres en Urologie, 15 (6), pp. 1106-1109 (French - abstract only)
Parker-Autry C, et al	Measuring outcomes in urogynecological surgery: "perspective is everything"	Int Urogynecol J (2013) 24:15-25
Parnell, BA, et al	Gentiofemoral and Perineal Neuralgia After Transobturator Midurethral Sling	Obstet Gynecol. 2012 Feb; 119(2 Pt 2):428-31
Peoples, AJ., et al	Determination of Volatile Purgeable Alogenated Hydrocarbons in Human Adipose Tissue and Blood Serum	Bull. Environm. Contam. Toxicol. 23, 244-249 (1979)
Persson J, Teleman P, et al	"Cost-analyzes based on a prospective, randomized study comparing laparoscopic colposuspension with a tension-free vaginal tape procedure. "	Acta Obstetricia et Gynecologica Scand 2002 Nov; 81(11):1066-73
Peters A, et al	Referral Patterns for Pelvic Floor Surgical Prosthesis Complications: From Symptom Onset and Initial Treatments to Evaluation at a Tertiary Care Center	Female Pelvic Med Reconstr Surg 2015;21: 116-120
Petri E, Ashok K	Complications of synthetic slings used in female stress urinary incontinence and applicability of the new IUGA-ICS classification	Euro Obstet & Gynecol and Reproductive Biology J 165 (2012) 347-351
Petros P	Letter to the Editor - A basis for long-term midurethral tape complications	Neurology and Urodynamics 2011;130: 199-200
Petros P, et al	Evolution of midurethral and other mesh slings - a critical analysis.	Neurology Urodynamics 2012;9999:1-7
Petros P, Richardson PA.	Midurethral tissue fixation system sling - a "micromethod" for cure of stress urinary incontinence - preliminary report.	Aust NZ J Obstet Gynaecol 2005;45:372-375
Petros PE and Ulmsten UI.	An integral theory of female urinary incontinence: Experimental and clinical considerations	Acta Obstet Gynecol Scand (1990) 69 Suppl 153:7-31
Pham S, Rodeheaver GT, et al	Ease of Continuous Dermal Suture Removal	J Emergence Med 1990; 8:539-543
Pham T, et al	New pelvic symptoms are common after reconstructive pelvic surgery	Am J Obstet Gynecol 2009;200:88.e1-88.e5.
Phé V, Zimmern P, et al	Outcome measures for SUI can we minimally agree?	World J Urol published online 20 March 2014
Phillips L, Flood CG, Schulz JA.	Case report of tension-free vaginal tape associated bowel obstruction and relationship to body habitus.	Int Urogyn J 2009;20:367-368

LITERATURE

Pierre, Gounon	Abstract "Histological analysis of peri prothetic tissues of mesh explanted for complication after SUI or POP surgery"	Universite de Nice Sophia Antipolis France
Pikaart DP, et al	Laparoscopic removal of pubovaginal polypropylene tension-free tape slings	JSLS (2006) 10:220-225
Pizarro-Berdichevsky JA, et al	Vaginal fibroblast inflammation by in vitro exposure to polypropylene type I mesh: an inert material?	Int Urogynecol J 2012; 23(Suppl 2): S110-S111
Pocock ST	The pros and cons of noninferiority trials	Fundamental & Clinical Pharmacol 17 (2003) 483-490
Polichetti M, et al	"IUGA Abs. 557 SUS(suburethral support): a new technique for short suburethral sling application"	Int Urogyn J 2009;20(Suppl 3):S477-478
Porena M, Costantini E, et al	Tension-free vaginal tape versus transobturator tape as surgery for stress urinary incontinence: results of a multicentre randomised trial.	Eur Urology, (2007)52:1481-1490
Portney S	Advertising and Promotion of Medical Devices	J Health Law (2006) 39(2) 265-282
Postlethwait RW	Long-Term Comparative Study of Nonabsorbable Sutures	Ann Surg (1970) 171(6): 892-898
Postlethwait RW	Five Year Study of Tissue Reaction to Synthetic Sutures	Ann Surg 190(1):54-57 (1979)
Presthus JB, VanDrie D, et al	Short-Term Assessment of MiniArc Single Incision for Treatment of Stress Urinary Incontinence	The Journal of Minimally Invasive Gynecology,15:28S-9S Abstract 103,01-Nov-08
Propex Geotextile Systems	Propex EB-405 Durability of Polypropylene	Propex EB-405
Public Citizen	Substantially Unsafe Medical Devices Pose Great Threat to Patients: Safeguards Must be Strengthened, Not Weakened	Public Citizen, February 2012
Pukall CF, et al	Neural correlates of painful genital touch in women with vulvar vestibulitis syndrome	Pain 2005 May; 115(1-2):118-27
Rabello MS, et al	The role of physical structure and morphology in the photodegradation behaviour of polypropylene	Polym Degrad Stab 1997; 56:55-73
Rader, CP, et al	Cytokine response of human macrophage-like cells after contact with polyethylene and pure titanium particles	J Arthroplasty 1999; 14(7):840-848
Ralph G, et al	The failed idea of a "gold standard"	Int Urogynecol J (2015) 26:1405-1406
Rardin CR, Moore R, et al	Recurrent Thigh Abscess with Necrotizing Fasciitis from a Retained Transobturator Sling Segment	The Journal of Minimally Invasive Gynecology,16:84-7,01-Jan-09
Ravve, C.	Principles of Polymer Chemistry	2000, Revised edition
Raz S	Expert: Synthetic materials are preferred for stress incontinence surgery	Urology Times April 08, 2007

LITERATURE

Rechberger T, et al	A randomized comparison between monofilament and multifilament tapes for stress incontinence surgery	Int Urogynecol J Pelvic Floor Dysfunct. 2003 Dec;14(6):432-6. Epub 2003 Nov 25
Rechberger T, Wrobel A, et al	"The tissue reaction to polypropylene mono-et multifilamentous tape used in surgical techniques of stress urinary incontinence treatment."	Gin Pol 2003;74(9):1008-1013
Rees PM, et al	Sexual function in men and women with neurological disorders ²	Lancet 2007; 369: 512-525
Reingruber E, et al	Identification of degradation products of antioxidants in polyolefins by liquid chromatography combined with atmospheric pressure photoionisation mass spectrometry	Polym Degrad Stab 2010; 95:740-745
Reisenauer C, Kirschniak A, et al	Transobturator tape inside-out. A minimally invasive treatment of stress urinary incontinence: surgical procedure and Anatomical considerations	European Journal of Obstetrics & Gynecology and Reproductive Biology(2006) 127: 123-129
Reisenauer C, Shiozawa T, et al	Anatomic study of prolapse surgery with nonanchored mesh and a vaginal support device	Obstet Gynecol 2010; 203:1.e1-1.e7
Rene' de la Rie E	Polymer Stabilizers. A Survey With Reference to Possible Applications in the Conservation Field	Studies in Conservation 33 (1988) 9-22
Renganathan A, Basu M, Duckett J.	A series of Advantage suburethral slings	J Obstet Gynaecol Aug 2011;31:521-523
Reynolds WS, et al	Obturator foramen dissection for excision of symptomatic transobturator mesh	J Urology (2012) 187: 1680-1684
Rezapour M, et al.	Tension-Free Vaginal Tape (TVT) in Stress Incontinent Women with Intrinsic Sphincter Deficiency (ISD) -- A Long-Term Follow-Up	Int Urogynecol J (2001) (Suppl 2): S12-S14
Rezapour, M., et al	Tension-Free Vaginal Tape (TVT) in Women with Mixed Urinary Incontinence -- A Long-Term Follow-Up	Int Urogynecol J (2001) (Suppl 2): S15-S18
Riachi L	A New Minimally Invasive Treatment Option for Stress Urinary Incontinence in Woman: TVT Abbrevio, a Shorter Sling with an Inside-out Transobturator Approach	Surg Technol Int (2013) 23: 176-180 ETH.MESH.12840997
Rice NT, Hu Y, et al	Pelvic mesh complications in women before and after the 2011 FDA public health notification	Female Pelvic Med Reconstr Surg (2013);19:33-338
Richter HE, Albo ME, et al	Retropubic versus Transobturator Midurethral Slings for Stress Incontinence	New England Journal of Medicine,362:2066-76,17-May-10
Ridgeway B, Arias B, and Barber M.	Variation of the obturator foramen and pubic arch of the female bony pelvis	The American Journal of Obstetrics & Gynecology,198:546.e1-4,01-May-08

LITERATURE

Rigaud J, Delavierre D, et al	Management of chronic pelvic and perineal pain after suburethral tape placement for urinary incontinence	Prog Urol. 2010 Nov;20(12):1166-74. Epub 2010 Oct 20. Review. French
Rignaud J, Pothin P, et al	Functional Results After Tape Removal for Chronic Pelvic Pain Following Tension-Free Vaginal Tape or Transobturator Tape	J Urology (2010) 184: 610-615
Rinne K, Laurikainen E, et al	A randomized trial comparing TVT with TVT-O: 12-month results.	The International Urogynecology Journal, 19:1049-54, 29-Mar-08
Riva D, Sacca V, Tonta A, et al.	T.V.T. versus T.O.T.: A Randomized Study at 1-year Follow-up.	International Urogynecology Journal, 2006 Sept 17(2) Supp: 57-100
Robert M, et al	Patient expectations, subjective improvement and objective cure: is there a difference between the transobturator tape and the tension free vaginal tape procedure? (Abstract)	Abstract 217
Robinson D., et al	What Women Want - Their Interpretation of the Concept of Cure	Journal of Pelvic Medicine & Surgery, Vol. 9 Issue 6, pp. 273-277, 2003
Robinson GA, et al	Motor neuron target selectivity and survival after prolonged axotomy	Restor Neurol Neurosci. 2013 Jan 1;31(4):451-60
Rodríguez LV, et al	Prospective analysis of patients treated with distal urethral polypropylene sling for symptoms of stress urinary incontinence: surgical outcome and satisfaction determined by patient driven questionnaires	J Urology 2003;170: 857-863
Rogers AS, et al	Physician knowledge, attitudes, and behavior related to reporting adverse drug events	Arch Intern Med 1988 Jul: 148(7): 1596-600
Rogers RG	Urinary Stress Incontinence in Women	N Engl J Med 2008; 358:1029-36
Rogo-Gupta L, et al	Complications of mesh-augmented pelvic organ prolapse and incontinence repairs: Case series of 319 procedures	University of California, Los Angeles ABSTRACT
Rogo-Gupta, L., Raz, S.	(2013). Pain Complications of Mesh Surgery.	In H.B. Goldman (Ed.), Complications of Female Incontinence and Pelvic Reconstructive Surgery (pp. 87-105): Humana Press.
Rogowski A, Bienkowski, et al	Mesh retraction correlates with vaginal pain and overactive bladder symptoms after anterior vaginal mesh repair	Int Urogynecol J (2013) 24:2087-2092
Rosa DS, et al	The use of optical microscopy to follow the degradation of isotactic polypropylene (iPP) subjected to natural and accelerated ageing	Polym Test 2005; 24:1022-1026
Rosch R, et al	Mesh implants In hernia repair. Inflammatory cell response in a rat model.	Eur Surg Res (2003)35(3): 161-6

LITERATURE

Ross S, et al	Ethical issues associated with the introduction of new surgical devices, or just because we can, doesn't mean we should	June JOGC Juin 2008 508-513
Ross S, Robert M, Lier D, et al	Surgical Management of Stress Urinary Incontinence in Women: Safety, Effectiveness, and Cost-Utility of Trans-Obturator Tape (TOT) versus Tension-free Vaginal Tape (TVT) Five Years After a Randomized Surgical Trial.	BMC Women's Health 2011, 11:34
Ross S, Robert M, Swaby C, et al	Transobturator Tape Compared With Tension-Free Vaginal Tape for Stress Incontinence	Obstetrics & Gynecology,114:1287-94,01-Dec-09
Roth, Ted M.	Management of persistent groin pain after transobturator sling	Int Urogynecol J (2007) 18:1371-1373 doi: 10.1007/s00192-007-0365-1
Rouen	ETH.MESH.00280338 Rouen Conceptual advances	
Roumeguère T, Quackels T, et al	Trans-obturator vaginal tape (TOT) for female stress incontinence: one year follow-up in 120 patients	European Urology (2005) 48: 805-809
Russell R	Zimmern cites shortcomings in published outcomes for anti-incontinence surgery	Newsroom Center Times, March 28-31, 2011
Sacomen D, et al	Effects of polyethylene particles of tissue surrounding knee arthroplasties in rabbits	J Biomed Mater Res Part B: Appl Biomater 1998; 43:123-130
Salvador MD, et al	Evaluation of chemical degradation of commercial polypropylene	J Mater Process Technol 2003;143-144: 693-697
Sand PK	Sumit Trial Outcomes: Clinical Insights Into Percutaneous Tibial Nerve Stimulation	Abstracts Female Pelvic Med & Reconstr Surg (2011) 17(5): S2
Sangster P, et al	Biomaterials in urinary incontinence and treatment of their complications	Indian J Urol 2010; 26(2): 221-229
Santavirta S, et al	Biocompatibility of polyethylene and host response to loosening cementless total hip replacement	Clin Orthop Relat Res 1993; 297:100-110
Santerre JP, et al	Enzyme-biomaterial interactions - effect of biosystems on degradation of polyurethanes	J Biomed Mater Res 1993; 27:97-209
Santoro M, Gorrie TM	Ethics and the Pharmaceutical Industry	Eds New York: Cambridge University Press 2005
Sarsotti C, et al	The transobturatoric tape procedure for stress urinary incontinence: results of an Argentinean multicenter experience	Int Urogynecol J (2007) 18 (Suppl I):S107-S244 Abst 375
Sayer T, Lim J., et al	Medium-term clinical outcomes following surgical repair for vaginal prolapse with tension-free mesh and vaginal support device	Int Urogynecol J DOI 10.1007/s00192-011-1600-3
Scales, J.T.	Tissue reactions to synthetic materials.	Proc R Soc Med, 46:647-652.
Scheiner D, Betschart C, et al	Retropubic TVT vs. Transobturator Outside-in TOT and TVT-O: One-year results from our prospective randomized study.	Neurourology and Urodynamics Eth.Mesh.00587443-00587444

LITERATURE

Scheiner DA, et al	Twelve months effect on voiding function of retropubic compared with outside-in and inside-out transobturator midurethral slings	Int Urogynecol J 2012 Feb;23(2):197-206
Schierlitz L, Dwyer P, et al	A randomized controlled study to compare tension free vaginal tape (TVT) and Monarc trans-obturator tape in the treatment of women with urodynamic stress incontinence (USI) and intrinsic sphincter deficiency (ISD): the three year follow up.	Int Urogynecol J (2010) 21 (Suppl 1):S1-S428
Schierlitz L, Dwyer PL, et al	Effectiveness of tension-free vaginal tape compared with transobturator tape in women with stress urinary incontinence and intrinsic sphincter deficiency: a randomized controlled trial	Obstet Gynecol (2008)112:1253-1261
Schierlitz LHE, Dwyer PL,et al	A randomised controlled study to compare tension free vaginal tape (TVT) and Monarc transobturator tape in the treatment of women with urodynamic stress incontinence (USI) and intrinsic sphincter deficiency (Abstract no. 032).	Int Urogynecol J (2010) 21 (Suppl 1):S1-S428
Schimpf, M.O. et al.	Sling surgery for stress urinary incontinence in women: a systematic review and metaanalysis	Am J Obstet Gynecol 211, 71 e1-71 e27 (2014)
Schneider, H.	Long-Term Performance of Polypropylene Geosynthetics	Durability and Aging of Geosynthetics, edited by R.M. Koerner, Elsevier Applied Science, 1989, pp. 95-109
Schoolenberg GE	A fracture mechanics approach to the effects of UV-degradation on polypropylene	J Mater Sci 1988; 23:1580-1590
Schoolenberg GE, et al	Ultra-violet degradation of polypropylene: 2. residual strength and failure mode in relation to the degraded surface layer	Polym 1991; 32(3):438-444
Schraut W, et al	TNF gene expression in monocytes of low and high responder individuals	Cytokine 1997; 9(3):206-211
Scottish News	Mesh surgery scandal: Controversial implants to be banned by Dumfries and Galloway health board	Scottish News article
Searti, M.	Tension-free Vaginal Tape for the Treatment of Urodynamic Stress Incontinence: Efficacy and Adverse Effects at 10- Year Follow-Up	Eur Urol 61 (2012) 939-946
Sekiguchi Y, et al	Outpatient mid urethral tissue fixation system sling for urodynamic stress urinary incontinence: 1-year results.	J Urol 2009;182:2810-283.
Serati M, Bauer R, Cornu JN, et al	"TVT-O for the treatment of pure urodynamic stress incontinence: efficacy, adverse effects, and prognostic factors at 5-year follow-up."	Eur Urol. (2013) 63(5):872-878

LITERATURE

Serati M, et al	TVT-O for the treatment of pure urodynamic stress incontinence: efficacy, adverse effects, and prognostic factors at 5-year follow-up	European Urology 63 (2013) 872-878
Serati M, Salvatore S, et al	Surgical treatment for female stress incontinence: What is the gold-standard procedure?	Int Urogynecol J 2009;20:619-621
Serati, M.	The Impact of the Mid-Urethral Slings for the Treatment of Stress Urinary Incontinence on Female Sexuality.	J Sex Med 2009; 6:1534-1542
Serbetci K, et al	Effects of reesterilization on mechanical properties of polypropylene meshes	Am J of Surg 2007; 194:375-379
Serels S, et al	Safety and efficacy of the Solyx single-incision sling for the treatment of stress urinary incontinence. Preliminary results	Urotoday Int J. 2011 Feb;4(1):art5
Serels S.	Cadaveric assessment of synthetic mid-urethral sling placement.	Open J Urol 2011;1:19-24
Sevegney MS, et al	FTIR Spectroscopic Investigation of Thermal Effects in Semi-Syndiotactic Polypropylene	J Polym Sci: Part B: Polym Physics 2005 43; 439-461
Shah, K, Nikolavsky, D, et al.	Surgical management of lower urinary mesh perforation after mid-urethral polypropylene mesh sling: mesh excision, urinary tract reconstruction and concomitant pubovaginal sling with autologous rectus fascia	Int Urogynecol J DOI 10.1007/s00192-013-2146-3 (2013)
Shah, S.M.	Impact of Vaginal Surgery For Stress Urinary Incontinence On Female Sexual Function: Is The Use Of Polypropylene Mesh Detrimental?	Urology (2005) 65: 270-274
Shameem A, et al	Measurement of transurethral bladder neck displacement during tension-free vaginal tape procedure	Int Urogynecol J (2011) 22:721-724
Sharifiaghdas F and Mortazavi N.	Tension-free vaginal tape and autologous rectus fascia pubovaginal sling for the treatment of urinary stress incontinence: a medium-term follow-up	Med Princ Pract 2008; 17:209-214
Shaw JS, et al	Decreasing transobturator sling groin pain without decreasing efficacy using TVT-Abbrevio	Int Urogynecol J 2015;26:1369-1372
Shaw JS, Jeppson PC, et al	Incidence of Postoperative Thigh Pain after TVT Obturator and TVT Abbrevio	J Min Invas Gynecol Abstracts (2014) 21: S52
Shaw JS, Rardin PC, et al	Effect of TVT-O Abbrevio on Post-Operative Groin Pain	J Min Invas Gynecol Abstracts (2014) 21: S27-28
Shepherd J, Feola A, et al	Uniaxial Tensile Properties of Seven Vaginally Implanted Meshes for Pelvic Organ Prolapse	IUGA Abstract
Shepherd JP, et al	Uniaxial biomechanical properties of seven different vaginally implanted meshes for pelvic organ prolapse	Int Urogynecol J (2012) 23:613-620

LITERATURE

Sheyn D, et al	Tobacco use as a risk factor for reoperation in patients with stress urinary incontinence: a multi-institutional electronic medical record database analysis	Int Urogynecol J 2015;26(9):1379-1384
Shindel AW, et al	Urethral slings placed by the transobturator approach: evolution in the technique and review of the literature	Curr Urol Rep 2005; 6(5):385-92
Silva, RA, et al	Degradation Studies of Some Polymeric Biomaterials: Polypropylene (PP) and Polyvinylidene Difluoride (PVDF)	Materials Science Forum Vols. 539-543 (2007): 573-576
Simsman AJ, Powell CR, Stratford	Suburethral sling materials: best outcome with autologous tissue	The American Journal of Obstetrics & Gynecology,193:2112-6,01-Dec-05
Sirls, LT, et al	Factors Associated With Quality of Life in Women Undergoing Surgery for Stress Urinary Incontinence	J Urology 2010; 184: 2411-2415
Sivanesan K	Comment on "tvf and tvf-obturator: comparison of two operative procedures"	Eur J Obstet Gynecol Reprod Biol 131 (2007) 87-90
Sivaslioglu AA, et al	A prospective randomized controlled trial of the transobturator tape and tissue fixation mini-sling in patients with stress urinary incontinence: 5-year results	J urology (2012) 188: 194-199
Skala C, Renezedder K, et al	The IUGA ICS classification of complications of prosthesis and graft insertion	Int Urogynecol J (2011) 22:149-1435
Skala CE, Renezedder K, et al	Mesh-complications following prolapse surgery: management and outcome	Euro Obstet & Tynecol and Reprod Biology J 159 (2011) 453-456
Skypunch, OW	Giant Papillary Conjunctivitis from an Exposed Prolene Suture	Can. J. Ophthalmology, 1986; 21(5:189-192)
Smith JJ, et al	Long-term outcomes and review of complications in 75 patients with Boston Scientific Advantage mesh in mid-urethral slings	www.bostonscientific.com
Smith PP, et al	Comparison of single-incision mid-urethral tape (Ophira™) and transobturator tape (Obtryx™) sub-urethral sling procedures for female stress urinary incontinence	JCMR 2013 5(5) 58-61
Smith R, et al	The enzymatic degradation of polymers in vivo	J Biomed Mater Res 1987; 21:991-1003
Smith, SE, et al	Materials characterization of explanted polypropylene hernia mesh: Patient factor correlation	Journal of Biomaterials Applications 2015; 0(0) 1-10
Song YF, Huang HJ, Xu B, et al	[Comparative study of tension-free vaginal tape and fascia lata for stress urinary incontinence]. [Chinese].	Zhonghua Fu Chan Ke Za Zhi. 2004 Oct;39(10):658-61. Chinese.
Songara, RK et al	Need for harmonization of labeling of medical devices: a review	J Adv Pharm Technol Res. 1020 Apr-Jun; 1(2): 127-144

LITERATURE

Sound Urological Associates	Women's Health webpage	Sound Urology Webpage http://soundurology.com/womens-health/ 2/16/2015
Spinsosa J, Dubuis P, and Riederer	Transobturator surgery for female stress incontinence: a comparative anatomical study of outside-in vs inside-out techniques	BJU International,100:1097-102,14-Sep-07
Stanton SL et al.	Some Reflections on Tension-Free Vaginal Tape - A New Surgical Procedure for Treatment of Female Urinary Incontinence	Int Urogynecol J (2001) (Suppl 2): S1-S2
Starr DS, Weatherford ST, et al	Suture Material as a Factor in the Occurrence of Anastomotic False Aneurysms	Arch Surg April 1979; 114: 412-415
Staskin DR, Plzak L	Synthetic Slings: Pros and Cons	Current Urology Reports 2002, 3:414-417
Steege, J.F.	Evaluation and Treatment of Dyspareunia	Obstetrics Y Gynecology: May 2009- Volume 113- Issue 5- pp 1124-1136
Stephens C, Zimmern PE	Expansion of role of web based networks to mesh complications	World J Urol published online 20 July 2014
Sternschuss G, et al	Post-implantation alterations of polypropylene in the human	J Urol 2012; 188: 27-32
Strasberg SM, et al	The accordion severity grading system of surgical complications	Annals of Surgery 2009; 250(2):177-186
Strömberg E, et al	The effect of biodegradation on surface and bulk property changes of polypropylene, recycled polypropylene and polylactide biocomposites	Inter Biodeterior Biodegradation 2009; 63:1045-1053
Strus M, et al	The in vitro effect of hydrogen peroxide on vaginal microbial communities	FEMS Immunol Med Microbiol 2006; 48:56-63
Strus, M., et al	Hydrogen Peroxide Produced by Lactobacillus Species as a Regulatory Molecule for Vaginal Microflora	Med Dosw Mikrobiol 2004;56:67-77
Sultana CJ, et al	The state of residency training in female pelvic medicine and reconstructive surgery	Int Urogynecol J (2007) 18:1347-1350
Sung VW, et al	Graft use in transvaginal pelvic organ prolapse repair	Obstet & Gynecol 2008; 112(5):1131-1142
Sung VW, Schleinitz MD,et al	Comparison of retropubic vs transobturator approach to midurethral slings: a systematic review and meta-analysis	The American Journal of Obstetrics & Gynecology,197:3-11,01-Jul-07
Svabik K, Martan A, et al	Ultrasound appearances after mesh implantation--evidence of mesh contraction or folding?	Int Urogynecol J (2011) 22:529-533
Svenningsen, Rune	Long-term follow-up of the retropubic tension-free vaginal tape procedure	Int Urogynecol J DOI 10.1007/s00192-013-2058-2
Sweat SD, et al	Polypropylene mesh tape for stress urinary incontinence: complications of urethral erosion and outlet obstruction	J Urology 2002; 168:144-146

LITERATURE

Szarnicki RJ	Polypropylene Suture Fracture	Ann Thorac Surg 1985 April; 39(4):400
Tahseen S, et al	Effect of transobturator tape on overactive bladder symptoms and urge urinary incontinence in women with mixed urinary incontinence	Obstet Gynecol 2009; 113:617-23
Tamai A, et al	TVT and TOT: a comparison between these two techniques based on our clinical experience	Urologia 2008 October-December; 75(4): 232-236
Tamussino K, Hanzal E, et al	Transobturator tapes for stress urinary incontinence: Results of the Austrian registry	Am J Obstet Gynecol 2007; 197:634e1-634e5
Tamussino K, Tammaa A, et al	TVT vs. TVT-O for primary stress incontinence: a randomized clinical trial	Int Urogynecol J (2008) 19 (Suppl 1):S1-S166
Tamussino KF, et al	Tension-Free Vaginal Tape Operation: Results of the Austrian Registry	Obstet Gynecol 2001;98:732-6
Tarcan T, et al	Safety and Efficacy of retropubic or transobturator midurethral slings in a randomized cohort of Turkish women	Urol Int Published online Aug 20, 2014
Taub, D., et al	Complications Following Surgical Intervention for Stress Urinary Incontinence: A National Perspective	Neurourology and Urodynamics 24:659-605 (2005)
Téllez Martínez-Fornés M, Fernánde	A three year follow-up of a prospective open randomized trial to compare tension-free vaginal tape with Burch colposuspension for treatment of female stress urinary incontinence2	Actas Urologicas Españolas 2009 Nov;33(10):1088-96
Teo R, Moran P, Mayne C, and Tince	Randomized Trial of Tension-free Vaginal Tape and Tension-free Vaginal Tape-Obturator for Urodynamic Stress Incontinence in Women.	Journal of Urology ,185: 1350-5 ,22-Feb-11
The American College of Obstetricia	"Grants, Sponsorships, and Other Support - 2009 "	The American Congress of Obstetricians and Gynecologists website,01-Jan-09
The British Association of Urologic	Synthetic Vaginal Tapes for Stress Incontinence Procedure-Specific Information for Patients	
Tijdink MM, Vierhout ME, et al	Surgical management of mesh-related complications after prior pelvic floor reconstructive surgery with mesh	Int Urogynecol J (2011) 22:1395-1404
Tincello D, Kenyon S, et al	Colposuspension or TVT with anterior repair for urinary incontinence and prolapse: results of and lessons from a pilot randomised patient-preference study (CARPET 1)	BJOG 2009; 116:1809-1814
Tincello DG, Botha T, et al	The TVT Worldwide Observational Registry for Long-Term Data: Safety and Efficacy of Suburethral Sling Insertion Approaches for Stress Urinary Incontinence in Women	Journal of Urology,186: 2310-5,01-Dec-11

LITERATURE

Tipton, JS	Obturator neuropathy	Curr Rev Musculoskelet Med. 2008 Dec;1(3-4):234-7
Tirlapur SA, Vlismas A, et al	Nerve stimulation for chronic pelvic pain and bladder pain syndrome: a systematic review	Acta Obstetrica et Gynecologica Scandinavica,,24-May-13
Tommaselli GA, D'Afiero A, et al	ICS Abs 791 Single incision tension-free vaginal tape (TVT-Secur®) in the treatment of female stress urinary incontinence.	International Continence Society Mtg 2010
Tommaselli GA, D'Afiero A, et al	Effect of Modified Surgical Technique for the Positioning of TVT-O on Post-Operative Pain	Int Urogynecol J (2011) 22 (Suppl 1) S110
Tommaselli GA, Di Carlo C, et al	Efficacy and Safety of TVT-Secur in the Treatment of Female Stress Urinary Incontinence: 1-year follow-up	The International Urogynecology Journal,21:1211-7,26-May-10
Tommaselli GA, et al	Comparison of TVT-O and TVT-Abbrevio for the surgical management of female stress urinary incontinence: a 12-months preliminary study	Int J Gyencol Obstet (2012) 119: Supp 3: S504
Tommaselli GA, Formisano C, Di Car	Effects of a modified technique for TVT-O positioning on postoperative pain: single-blind randomized study.	Int Urogynecol J. (2012) 23:1293-9.
Touboul, C.	Perineal approach to vascular anatomy during transobturator cystocele repair	BJOG 2009; 116:708-712
Trabucco A, et al	A novel composite sling for the treatment of stress urinary incontinence: first clinical experience	J Pelvic Medicine & Surg 2004; 10(2):63-70
Trabucco AF, et al	Nowa beznapiowa tasma T- sling w leczeniu wysitkowego nietrzymania moczu	Foreign Journal
Trindade MCD, et al	Proinflammatory mediator release in response to particle challenge: Studies using the bone harvest chamber	Biomed Mater Res Appl Biomater 1999; 48:434-439
Trivedi, et al	Understanding Female Urinary Incontinence and Master Management	S. Narayan & Sons 2014
Tseng LH, Wang AC, Lin YH, et al	Randomized comparison of the suprapubic arc sling procedure vs tension-free vaginal taping for stress incontinent women	The International Urogynecology Journal,16:230-5,27-Oct-04
Tunn, R.	Sonomorphological Evaluation of Polypropylene Mesh Implants After Vaginal Mesh Repair in Women With Cystocele or Rectocele	Ultrasound Obstetrics Cynecol 2007; 29:449-452
Turon TJ, et al	Effect of stabilizer and pigment on photo-degradation depth profiles in polypropylene	Polym Degrad Stab 2001; 74:559-568
Turut P, Florin P, et al	Les Complications Dues Au Prolene	Bull.Soc.Opht.France 1981: 8-9
Twiss C and Raz S.	Complications of synthetic mid-urethral slings	laborie.com,,01-Mar-08
Tyan Y, et al	Assessment and characterization of degradation effect for the varied degrees of ultra violet radiation onto the collagen-bonded polypropylene non-woven fabric surfaces	Biomater 2002; 23:65-76

LITERATURE

Tzartzeva K, et al	In-depth nano-investigation of vaginal mesh and tape fiber explants in women	IUGA 2014 Abstract 366
UCLA	Clinical Updates - Surgical mesh for pelvic organ prolapse repair the subject of FDA warning	UCLA Clinical Updates webpage 9/19/2012
Ulmsted U, et al	An Ambulatory Surgical Procedure Under Local Anesthesia for Treatment for Femals Urinary Incontinence	Int Urgynecol J (1996) 7:81-86
Ulmsten U, Falconer C, et al	A multicenter study of tension-free vaginal tape (TVT) for surgical treatment of stress urinary incontinence.	The International Urogynecology Journal,9:210-213,20-Jun-05
Ulmsten U, Henriksson L, et al	An Ambulatory Surgical Procedure Under Local Anesthesia for Treatment of Female Urinary Incontinence	The International Urogynecology Journal,7:81-6,01-Jan-96
Ulmsten U.	An Introduction to Tension-Free Vaginal Tape (TVT) - A New Surgical Procedure for Treatment of Female Urinary Incontinence	Int Urogynecol J (2001)(Suppl 2):S3-S4
Ulmsten U., et al	Reprint: A Multicenter Study of Tension-Free Vaginal Tape (TVT) for Surgical Treatment of Stress Urinary Incontinence	Int Urogynecol J (1998) 9:210-213 Eth.Mesh.00145084-00145088
Ulmsten, et al	A three-year follow up of tension free vaginal tape for surgical treatment of remale stress urinary incontinence	Br J Obstet Gynaecol (1999)106: 345-350
Unger, CA, et al	Outcomes following treatment for pelvic floor mesh complications	Int Urgynecol J (2014) 25:745-749
Usher FC, et al	Poly Monogilament. A new, biologically inert suture for closing contaminated wounds	JAMA 1962; 179(10) :780-782
Ustün Y, Engin-Ustün Y, et al	Tension-free vaginal tape compared with laparoscopic Burch urethropexy	J Am Assoc Gynecol Laparosc. 2003 Aug;10(3):386-9
Valentim-lourenco A, et al	"TORP- comparing the efficacy, execution and early complications of TVT and TVT-0"	International Urogynecology Journal
Valpas A, Kivelä A, et al	Tension-free vaginal tape and laparoscopic mesh colposuspension for stress urinary incontinence	Obstetrics & Gynecology, 2004 July; 104(1):42-49
Van Winkle W Jr, et al	Effect of suture materials on healing skin wounds	Surg Gynecol Obstet 1975; 140(1):7-12
Vassallo, BJ., et al	Management of Iatrogenic Vaginal Constriction	Obstet Gynecol. 2003 Sept; 102(3): 512-20
Velemir L, Amblard J, Jet al	Urethral erosion after suburethral synthetic slings: risk factors, diagnosis, and functional outcome after surgical management	int Urogynecol J (2008) 19: 999-1006
Velemir L, et al	Transvaginal mesh repair of anterior and posterior vaginal wall prolapse: a clinical and ultrasonographic study	Ultrasound Obstet Gynecol (2010) ETH.MESH.01192895
Versi E	"Gold standard" is an appropriate term	BMJ 1992; 305:187

LITERATURE

Vervest HAM, Bisseling TM, et al	"The prevalence of voiding difficulty after TVT, its impact on quality of life, and related risk factors."	Int Urogynecol J 2007;18:173-182
Viereck, Volker ; Rautenberg, et al	Midurethral Sling Incision: Indications and Outcomes	Int Urogynecol J (2013) 24:645-653
Voeller, GR	New Developments in Hernia Repair	Surg Technol XI: 111-116
Vollebregt, A., et al	Bacterial Colonisation of Collagen-Coated Polypropylene Vaginal Mesh: Are Additional Intraoperative Serility Procedures Useful?	Int Urogynecol J Pelvic Floor Dysfunct. 2009 Nov;20(11):1345-51
Von Theobald P, Zimmerman CW, et al	New Techniques in Genital Prolapse Surgery	2011 XII, 310 p, Hardcover ISBN: 978-1-84885-135-4
Voskerician G, et al	Effect of biomaterial design criteria on the performance of surgical meshes for abdominal hernia repair: a pre-clinical evaluation in a chronic rat model	J Mater Sci: Mater Med (2010) 21:1989-1995
Wadie BS, Edwan A, and Nabeeh AM.	Autologous fascial sling vs polypropylene tape at short-term followup: a prospective randomized study	J Urology, 2005 Sept; 174:990-993
Wadie BS, Mansour A, et al	Minimum 2-year follow-up of mid-urethral slings, effect on quality of life, incontinence impact and sexual function	Int Urogynecol J (2010) 21:1485-1490
Wai CY.	Surgical treatment for stress and urge urinary incontinence.	Obstet Gynecol Clin N Amer 2009;36:509-519
Wai, C.Y.	Patient Satisfaction After Midurethral Sling Surgery for Stress Urinary Incontinence.	Obstet Gynecol (2013) 121:1009-1016
Walsh CA.	TVT-Secur mini-sling for stress urinary incontinence: a review of outcomes at 12 months.	BJU International,108:652-7,14-Jul-11
Walter JE.	SOGC Technical Update No. 254: Transvaginal Mesh Procedures for Pelvic Organ Prolapse. Society of Obstetricians and Gynaecologists of Canada	Journal of Obstetrics and Gynaecology Canada,33:168-74 ,01-Feb-11
Walters, MD	Percutaneous Suburethral Slings: State of the Art	Presented at the conference of the American Urogynecologic Society, Chicago, 29 pages (Oct. 2001)
Waltregny D,	New Surgical Technique for Treatment of Stress Urinary Incontinence TVT-Abbrevio: From Development to Clinical Experience	Surg Technol Int (2012) 22:149-157
Waltregny D, de Leval J.	The TVT-obturator surgical procedure for the treatment of female stress urinary incontinence: a clinical update.	Int Urogynecol J (2009) 20:337-348
Waltregny D, Gaspar Y, et al	TVT-O for the treatment of female stress urinary incontinence: Results of a prospective study after a 3-year minimum follow-up	European Urology,53:401-10,21-Aug-07

LITERATURE

Waltregny D, Reul O, et al	Inside out transobturator vaginal tape for the treatment of female stress urinary incontinence: interim results of a prospective study after a 1-year minimum followup.	J Urol. 2006 Jun;175(6):2191-5.
Waltregny D, Thomas A, et al	Three year results of a prospective randomized trial comparing the original inside-out transobuturator (TVT-O™) Procedure with a modified version of using a shortened tape and reduced dissection for the treatment of female stress urinary incontinence	ICU Abstract 254
Waltregny TA, DeLeval J	One year results of a prospective randomized trial comparing the original inside-out transobturator (TVT-O™) procedure and a modified version using a shortened tape and reduced dissection for the treatment of female stress urinary incontinence [abstract]	Int Urogynecol J (2010) 21 (Suppl 1) S219-S221 IUGA, Abst 153
Wang AC and Chen MC.	Comparison of tension-free vaginal taping versus modified Burch colposuspension on urethral obstruction: a randomized controlled trial	Neurourology and Urodynamics 22:185-190 (2003)
Wang AC, Lee L, Lin C, et al	A histologic and immunohistochemical analysis of defective vaginal healing after continence rapping procedures: A prospective case-controlled pilot study2	American Journal of Obstetrics and Gynecology (2004) 191, 1868-74
Wang F, Song Y and Huang H.	Prospective randomized trial of TVT and TOT as primary treatment for female stress urinary incontinence with or without pelvic organ prolapse in Southeast China	Arch Gynecol Obstet. 2010 Feb; 281(2) 279-86
Wang W, Zhu L and Lang J.	Transobturator tape procedure versus tension-free vaginal tape for treatment of stress urinary incontinence	International Journal of Gynecology & Obstetrics 104 (2009) 113-116
Wang YJ, Li FP, Wang Q, et al	Comparison of three mid-urethral tension-free tapes (TVT, TVT-O, and TVT-Secur) in the treatment of female stress urinary incontinence: 1-year follow-up.	Int Urogynecol J. 2011 Nov;22(11):1369-74. doi: 10.1007/s00192-011-1445-9. Epub 2011 May 13
Wang, AC	A microbiological and immunohistochemical analysis of periurethral and vaginal tissue in women with de novo urge symptoms after mid-urethral sling procedures—a prospective case-controlled study.	Int Urogynecol J (2008) 19:1145-1150
Ward K, et al	Minimally invasive synthetic suburethral slings: emerging complications	The Obstetrician & Gynaecologist 2005;7:223-232
Ward KL and Hilton P et al	A prospective multicenter randomized trial of tension-free vaginal tape and colposuspension for primary urodynamic stress incontinence: Two-year follow-up	The American Journal of Obstetrics & Gynecology,190:324-31,01-Feb-04

LITERATURE

Ward KL and Hilton P.	Tension-free vaginal tape versus colposuspension for primary urodynamic stress incontinence: 5-year follow up	BJOG 2008;115:226-233
Weber AM, et al	The standardization of terminology for researchers in female pelvic floor disorders	Int Urogynecol J (2001) 12: 178-186
Wei JT, et al	A Midurethral Sling to Reduce Incontinence after Vaginal Prolapse Repair	N Engl J Med. 2012 June 21; 366(25): 2358-2367. doi:10.1056/NEJMoa1111967.
Welk B, et al	Removal or revision of vaginal mesh used for the treatment of stress urinary incontinence	JAMA Surg. doi:10.1001/jamasurg.2015.2590 Published online September 9, 2015.
Westermann L, Brown A, et al	Delayed Presentation of an Enterocutaneous Fistula After Tension-Free Vaginal Tape Sling	Female Pelvic Reconstr Surg 2011; 17: 258-259
White RA, et al	Histopathologic observations after short-term implantation of two porous elastomers in dogs	Biomater 1981; 2:171-176
White WM, et al	Robotic sacral colpopexy	Chapter 5; P. Dasgupta et al. (eds.), New Technologies in Urology, 37 DOI: 10.1007/978-1-84882-178-1_5, © Springer-Verlag London Limited 2010
Whiteside JL and Walters MD.	Anatomy of the obturator region: relations to a trans-obturator sling	The International Urogynecology Journal,15:223-6,24-Feb-04
Wijffels SAM, et al	Transurethral mesh resection after urethral erosion of tension-free vaginal tape: report of three cases and review of literature	Int Urogynecol J (2009) 20:261-263
Willard, FH, et al	The Neuroanatomy of Female Pelvic Pain	Pain in Women: A Clinical Guide, Chapter 2
Willert HG, et al	Osteolysis in Alloarthroplasty of the hip. The role of ultra-high molecular weight polyethylene wear particles	Clin Orthop Relat Res 1990; 258:95-107
Williams	Mechanisms of biodegradation of implantable polymers	Clin Mater 1992;10:9-12
Williams D.	Review Biodegradation of surgical polymers	Journal of Materials Science. 1982; 17:1233-1246
Williams DF	On the Mechanisms of Biocompatibility	J.Biomaterials.2008.04.023:1-13
Williams DF, et al	Biodeterioration/Biodegradation of Polymeric medical devices in situ	Inter Biodeterior Biodegradation 1994; 34(2): 95-130
Williams, DF, et al	The biodegradation of surgical polymers	Polyurethanes in Biomedical Engineering edited by H. Planck, et al, Elsevier Science Publishers B.V., Amsterdam, 1984

LITERATURE

Wilson, C, et al	Short-term efficacy of transobturator sling in women veterans with a history of sexual trauma	MAAUA 68th Annual Meeting Abstracts (2010)
Withagen MI, Milani AL, et al	Trocar-guided mesh compared with conventional vaginal repair in recurrent prolapsed: a randomized controlled trial.	Obstetrics & Gynecology,117:242-50 ,01-Feb-11
Wolter CE, Starkman JS, et al	Removal of transobturator midurethral sling for refractory thigh pain.	Urology (2008) 72: 461.e1-461.e3
Wood,AJ	Materials characterization and histological analysis of explanted polypropylene, PTFE, and PET hernia meshes from an individual patient	J Mater Sci: Mater Med (2013) 24:1113-1122
Wróbel A, et al	Clinical effectiveness of transobturator midurethral sling (T-sling) with additional 2-point tape fixation performed on an outpatient and inpatient basis	Finekol Pol 2014;85(11):833-837
Wu JM, Kawasaki A, et al	"Predicting the number of women who will undergo incontinence and prolapse surgery, 2010 to 2050. "	The American Journal of Obstetrics & Gynecology,205:230.e1-5 ,02-Apr-11
Wyczolkowski, M., et al	Reoperation After Complicated Tension-Free Vaginal Tape Procedures	The Journal of Urology, Vol 166, 1004-1005 (Sept 2001)
Yahi YH, et al	Electronic Microscopy Study of Alterations of Meshes Explanted for Complications in SUI or POP Surgery	Int Urogynecol J 2007; 18(Suppl 1): S6
Yakimets I, et al	Effect of photo-oxidation cracks on behaviour of thick polypropylene samples	Polym Degrad Stab 2004; 86:59-67
Yang C, et al	Presentation Number: Oral Poster 18 Anchor extraction forces for single-incision slings: strength comparison in a rabbit model	Female Pelvic Med & Reconstr Surg (2011) 17(5)2:S92
Yang CH, Chan PH, Lai SK, et al	A retrospective study comparing tension-free vaginal tape and transobturator suburethral tape for surgical treatment of female stress urinary incontinence --- a preliminary report.	J Chin Med Assoc. 2007 Dec;70(12):541-4. doi: 10.1016/S1726-4901(08)70057-1.
Yang CQ, et al	Photo and thermal-oxidation of the nonwoven polypropylene fabric studies by FT-IR photoacoustic spectroscopy	J Appl Polym Sci 1994; 51:389-397
Zahn C et al	Anatomic comparison of two transobturator tape procedures.	Obstet Gynecol 2007;109:701-6.
Zhang Y, Jiang M, Tong XW, et al	The comparison of an inexpensive-modified transobturator vaginal tape versus TVT-O procedure for the surgical treatment of female stress urinary incontinence.	Taiwan J Obstet Gynecol. 2011 Sep;50(3):318-21. doi: 10.1016/j.tjog.2011.01.033
Zhao AH, Agger MP, et al	Cellular interactions with biomaterials: in vivo cracking of pre-stressed Pellethane 2363-80A	J Biomed Mater Res (1990) 24: 621-637

LITERATURE

Zhao AH, McNally AK, et al	Human plasma δ 2-macroglobulin promotes in vitro oxidative stress cracking of Pellethane 2363-80A: In vivo and in vitro correlations	J Biomed Mater Res (1993) 27: 379-389
Zhong C, Yuan C, Guang-hui D, et al	Comparison of three kinds of midurethral slings for surgical treatment of female stress urinary incontinence.	Urologia 2010;77(1):37-42
Zhu L, Lang J, Hai N, and Wong F.	Comparing vaginal tape and transobturator tape for the treatment of mild and moderate stress incontinence	International Journal of Gynecology & Obstetrics (2007) 99, 14-17
Zolotarevova E, et al	Distribution of polyethylene wear particles and bone fragments in periprosthetic tissue around total hip joint replacements	Acta Biomaterialia 2010; 6(9): 3595-3600
Zoorob, D. and M. Karram	Management of mesh complications and vaginal constriction: a urogynecology perspective	Urol Clin North Am, 2012. 39(3): p.413-8
Zuckerman DM., et al	Medical Device Recalls and the FDA Approval Process	Arch Intern Med 2011;17(11): 1006-1011 Published Online February 14, 2011
Zugor V, Labanaris AP, et al	"TVT vs. TOT: a comparison in terms of continence results, complications and quality of life after a median follow-up of 48 months. "	Int Urol Nephrol.
Zullo MA, Plotti F, et al	One-year follow-up of tension-free vaginal tape (TVT) and trans-obturator suburethral tape from inside to outside (TVT-O) for surgical treatment of female stress urinary incontinence: a prospective randomised trial.	European Urology,51:1376-82,07-Nov-06
Zumbe J., Porres D., Degiorgis PL.	Obturator and thigh abscess after transobturator tape implantation for stress urinary incontinence.	Urol Int. (2008); 81:483-485
Zwarenstein M, et al	Improving the reporting of pragmatic trials: an extension of the CONSORT statement	BMJ 2008; 337:12390
Zycynski HM, Carey MP, et al	One-year clinical outcomes after prolapse surgery with nonanchored mesh and vaginal support device	Am J Obstet Gynecol 2010; 203:587.e1-8